



California University of Pennsylvania

POLICY: IRB & Training Requirements

A. Purpose & Scope

To describe the requirements related to the Institutional Review Board (IRB) for all researchers as mandated by the university's Federal wide Assurance (FWA).

The primary goal of the IRB is the protection of research participants. The IRB does not endorse the quality of the research and approval does not absolve researchers from the responsibility to monitor and maintain the project within their professional guidelines. The ultimate responsibility for the ethical conduct of research remains with the researchers.

According to the Office for Human Research Protections (OHRP) under the Department of Health and Human Services, every investigator applying to the IRB for research involving human research participants must document that they have completed the OHRP or similar education and training program regarding human research protections.

B. Definition(s)

Federal wide Assurance for the Protection of Human Subjects (FWA) – a written assurance through which the university has committed to the federal Department of Health and Human Services (HHS) that it will comply with all the requirements in the HHS Protection of Human Subjects regulations.

Institutional Review Board (IRB) – an independent standing committee, constituted according to federal regulations, with the authority to approve, to require modification as a condition of approval, and to disapprove proposed and ongoing research activities.

C. Policy

All members of the California University of Pennsylvania community who engage in activities that are classified as research involving human participants must submit their research proposals to the IRB for review and approval.

Any organization conducting research in which members of the California University of Pennsylvania community are purposefully recruited as research participants must have their research project approved by the California University of Pennsylvania IRB.

To maintain compliance with the provisions of the university's existing Federal wide Assurance (FWA), no research involving human participants may be undertaken at California University of Pennsylvania without prior review by the IRB. Failure to observe the policies and procedures described herein will be considered serious misconduct, subject to sanctions including possible recommendations for termination of faculty appointment, student enrollment or other affiliation with California University of Pennsylvania.

Every investigator at California University of Pennsylvania applying to the IRB for research involving human participants must document that they have completed appropriate training. The California University of Pennsylvania IRB will not approve any proposed or ongoing research involving human subjects until the investigator submits a certificate of completion from an approved training program, which is outlined on the IRB web page.

D. Procedure(s)

1. Investigators whose research involves human participants must complete an approved course of training in human participant protection. Visit the California University of Pennsylvania IRB web site for details. Retain a copy of the documentation to verify completion of the training. No IRB application will be reviewed if a copy of the certificate is missing from the submission.
2. Complete the IRB Review Request Form. Instructions on what is required in the application are contained in the checklists that are part of the form. Completion of the checklists is mandatory.
3. Include copies of consent forms (or cover letters for surveys, questionnaires and interviews). Use of the checklists will ensure that the content of these forms/letters meets the guidelines.
4. The IRB Review Request Form must be signed by the principal researcher(s). For student research, the form must be signed by the student researcher(s) and the faculty sponsor. The application will not be reviewed if any of these signatures is missing.
5. Submit the IRB Review Request Form via email to: instreviewboard@calu.edu a minimum of 20 business days prior to the proposed initiation of the research investigation (Note: additional time may be required if modifications or revisions are needed). All research proposals must be approved by the IRB before any data are collected by the researcher(s). The IRB will not approve any research effort after the fact.
6. In the case of multiple investigators at multiple sites, the applicants at California University of Pennsylvania should contact the Chair of the IRB for specific guidance.

E. Effective Date: *Approved by UCC on May 20, 2015*

Updated Date:

Amended Date: