

# DOES MY RESEARCH PROJECT NEED IRB REVIEW?

Instructions: Use this worksheet to help you determine whether the proposed project requires submitting a complete application for review by the Institutional Review Board (IRB). This worksheet is based on OHRPs [Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?](#) Students: Complete this worksheet with your faculty advisor. All: Retain the worksheet in your personal research records.

Completed By: _____	Date: _____
Project Title: _____	_____
Details: _____	_____
Attachment Other: _____	_____

1. Is the research "a systematic investigation including development, testing and evaluation"?

A "systematic investigation" refers to the strategy of the study (systematically organized so you can test your hypothesis or exploring cause and effect relationships among a set of factors and your topic), as well as rigor. "Development, testing and evaluation" refers to the components of a research design including your procedures, methods and instruments. In other words: Is your research designed to develop, and/or test, and/or evaluate the procedures, methods, and instruments? Research projects which are designed as common biographical research including ethnographies, oral histories, situational or event case studies, and journalism are typically not designed as a systematic investigation. Not sure? Continue to #2.

- Yes, or Not Sure? Continue to question #2.
- No → Stop. Projects that are not "a systematic investigation" are not considered Human Subjects Research by OHRP and do not need to be reviewed by the IRB. However, see question #6 for Additional Precautions evaluation.

2. Is the research designed to "develop or contribute to generalizable knowledge"?

"Develop or contribute to generalizable knowledge" refers to making the components of a research design (procedures, methods, and instruments) as well as your analyzed findings available for other professionals and/or academics to peer review, replicate and utilize. Traditionally this occurs when publishing or presenting at a professionally refereed venue, conference or competition but it may also occur through new-media methods of professional discourse. Projects which are disseminated exclusively at CSU in a class, group, or projects which are designed to evaluate and/or improve the quality of programs or services, such as teacher-assessment, are typically not designed to develop or contribute to generalizable knowledge. Not sure? Continue to #3.

- Yes, or Not Sure? Continue to question #3.
- No → Stop. Projects that are not designed to "develop or contribute to generalizable knowledge" are not considered Human Subjects Research by OHRP and do not need to be reviewed by the IRB. However, see question #6 for Additional Precautions evaluation.

3. Does the research involve intervention or interaction with living individuals?

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Deceased individuals are not considered "human subjects" by CHRP.

- Yes, or Not Sure? Submit an IRB application.
- No: Continue to question #4.

4. Is the research utilizing existing data which contains individually identifiable private information?

The identity of the human subject is or may be readily ascertained by the investigator or associated with the information collected and is about behavior that occurs in a context in which the subject can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

- Yes, or Not Sure? Submit an IRB application.
- No: Continue to question #5.

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5. Is there any possibility that the researcher or collaborators (e.g.: student assistants, professional partners, etc.) could ascertain the identity of a living individual from the data utilized at any point during the course of research?
- Yes: Go to Human Subjects Research — REQUIRES IRB REVIEW (below).
  - No -> Stop. Using non-identifiable private information is not considered Human Subject Research by OHFP. If your research utilizes data which is irrevocably de-identified, or coded in such a way that the researcher and collaborators cannot ascertain the identity of a living individual, the project does not need to be reviewed by the IRB. However, see question #6 for Additional Precautions evaluation.

## 6. Additional Precautions

- A. Do you or another entity (e.g.: agency, sponsor, or faculty adviser) want to retain the option of utilizing the research design and findings for future "development or contribution to generalizable knowledge"?
- Yes, or Not Sure? If you answered "Yes, or Not Sure" to questions #1 and #3 and "No" to question #2: Go to Human Subjects Research — REQUIRES IRB REVIEW (below). If you answered in any other combination: Continue to question #6-B.
  - No: Continue to question #6-B.
- B. Do you need formal notification from an IRB stating the protocol has been reviewed in order to meet documentation requirements for another entity (e.g.: agency, sponsor, or publisher)?
- Yes: Go to Human Subjects Research — REQUIRES IRB REVIEW (below).
  - No: Continue to question #6-C.
- C. Does the project involve participants from a protected or vulnerable population?
- Yes, or Not Sure? Your project may pose a Special Risk. Contact the IRB office at (310) 243-2136 or [irb@csudh.edu](mailto:irb@csudh.edu).
  - No: Continue to question #6-D.
- D. Does the project collect data or personally identifiable private information which may cause harm (e.g.: psychological, physical, legal, social, and/or economic) during collection or if it's ever revealed?
- Yes, or Not Sure? Your project may pose a Special Risk. Contact the IRB office at (310) 243-2136 or [irb@csudh.edu](mailto:irb@csudh.edu).
  - No: Continue to question #6-E.
- E. Do the research activities pose a risk to you as the researcher?
- Yes, or Not Sure? Your project may pose a Special Risk. Contact the IRB office at (310) 243-2136 or [irb@csudh.edu](mailto:irb@csudh.edu).
  - No -> Stop. If you answered "No" to all questions under #6 (A-E): You have completed this form.

### Human Subjects Research

Go to [IRB@CSUDH](mailto:IRB@CSUDH) (<http://www4.csudh.edu/research/research-compliance/irb/>) for guidance and forms. Questions: (310) 243-2136