

The logo features the text "UCI Office of Research" centered within a large, light blue, multi-lobed circular graphic that resembles a stylized flower or a complex geometric pattern. The background is a solid, darker blue.

UCI Office of
Research

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Discussion Topics

- What is the IRB?
- What Requires IRB Review?
 - Definitions of Human Subjects and Research
 - Quality Improvement / Program Evaluation
- Submitting to the IRB?
 - Materials / Study Documents
 - Level of Risk
 - Tips for New Investigators

What is the Institutional Review Board?

- Protecting Participants Research
- 5 Committees
 - Biomedical & SBE
 - Risks Levels
- Membership

What Requires IRB Review?

DHHS (OHRP) Definition

45 CFR 46.102(f) Human Subject - a *living individual about whom* an investigator (faculty, staff, or student) conducting research obtains **(1) data through intervention or interaction with the individual**, or **(2) identifiable private information**.

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 researcher and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record information). Private information must be individually identifiable.

Individually identifiable includes where the identity of the subject is or may be ascertained by the researcher or associated with the information.

DHHS (OHRP) Definition

45 CFR 46.102(d) Research - a (1) *systematic investigation*, including research development, testing and evaluation, (2) *designed to develop or contribute to generalizable knowledge*.

A '**systematic investigation**' involves a plan which incorporates collection of data, either quantitative or qualitative, or specimens; and analysis to answer a question.

Activities '**designed to develop or contribute to generalizable knowledge**' are those activities designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings.

***NOT* Generalizable Knowledge**

- Biographies / Oral History
- Quality Assurance Activities
- Quality Improvement
- Program / Department Evaluation
- Results specific to UCI Community only
- Intent?

Submitting to the IRB

- Involves Human Subjects Research
- Activities
 - Interview / Focus Group
 - Audio Record
 - Surveys / Questionnaires
- Risk to Participants



Level of Risk

- Virtually No Risk – Exempt Level
- Minimal Risk – Expedited Level
 - Criminal / Civil liability
 - Reputation / Social Standing
 - Employability / Financial Standing
- Full-Committee (greater than minimal risk)

Tips for Submitting

- Complete Tutorials
- Submit *all* Study Documents
- Answer Instructional Prompts
- Plan Ahead

THANK YOU!!!