



Overview of Human Subjects Research

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What is Research?

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

45 CFR 46.102 (d)





What is A Human Subject?

A living individual about whom an investigator (professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, or
- Identifiable private information

45 CFR 46.102(f)





45 CFR 46
Code of Federal Regulations
TITLE 45 PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES, PART 46
PROTECTION OF HUMAN SUBJECTS
(The Common Rule)

HHS regulations at 45 CFR part 46 stipulate substantive and procedural requirements for investigators and institutions engaged in HHS-supported or -conducted research.

University of California policy requires the application of 45 CFR 46 to all humans subjects research, regardless of funding source.



Understanding the IRB

An independent campus-wide committee charged with the review of human subjects research to assure that the rights and welfare of human research participants are adequately protected.





IRB Responsibilities

- Reviews and approves or disapproves all human subject research activities, including study modifications
- Has the authority to suspend or terminate previously approved research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to subjects.



IRB Process

Types of Review

- **Exempt** (45 CFR 46.101(b) – minimal risk and falls into one of six exemption categories
- **Expedited** (45 CFR 46.110) – minimal risk and all procedures fall into one of nine categories
- **Full Committee** – all studies that do not qualify for exempt or expedited review

The IRB makes this decision!



Informed Consent

What it is:

- ✓ An ongoing process of communication and mutual understanding

What it isn't:

- ✓ A piece of paper
- ✓ A moment in time
- ✓ A legal contract



Informed Consent

- **Obtain legally effective informed consent from the subject or subject's legally authorized representative**
- **In a language understandable to the subject**
- **Allows subject to consider whether or not to participate, and minimizes coercion**
- **Subject does not waive any legal rights**





Elements of a Consent form

1. Statement that the study involves research
2. Reasonably foreseeable risks or discomforts
3. Reasonably foreseeable benefits - subject or others
4. Appropriate alternatives procedures or treatments
5. Statement describing the extent of confidentiality
6. Compensation for research related injury
7. Whom to contact to answer questions and subject's rights
8. Statement that participation is voluntary



Recruitment is part of the Consent Process

- Recruitment plans, “Public Service” announcements, ads and flyers are usually the beginning of the informed consent process.
- All recruitment plans and documents must be reviewed and approved by the IRB prior to implementation or display





Investigator* Responsibilities

Has primary responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of their institution's Assurance.

***Includes student investigators!**





FERPA & Research

Family Educational Rights & Privacy Acts (FERPA)

- Applies when accessing educational records for research purposes.
- Additional Consent is required:
 - Specifies the records to be disclosed
 - States the purpose of the disclosure
 - Identify the party to whom the disclosure is to be made
 - Include a dated student signature
 - Exceptions available: *accessing directory information only; release to authorized reps of State/local educational authorities; or release to organizations conducting studies (on behalf of educational agencies) to improve instruction, develop/validate/administer tests, administer student aid programs*



FERPA & Research

Sample FERPA Release Language

As a result of your student status, your records and personal information are protected by the Family Educational Rights and Privacy Act (FERPA). Since the data to be used may includes student record information (specify information to be accessed) you will be asked to authorize the release/use of this information.

In accordance with the Family Educational Rights and Privacy Act of 1974 (FERPA), I, the undersigned, hereby authorize (give the name of the principal investigator), the primary research investigator, to use my (Name of course) course grade:

I understand further that (1) I have the right not to consent to the release of my education records; (2) I have the right to receive a copy of such records upon request; (3) and that this consent shall remain in effect unless revoked by me. I may revoke this right at any time, but that any such revocation shall not affect information previously accessed by the research investigator prior to the receipt of any such written revocation



Research vs. Program Assessment

	Research	PA/QI/QA
Purpose	To make a careful, systematic, patient study, investigation or probing inquiry in some field of knowledge.	Evaluate a process, program, or system
Starting Point	There is a formal research question, literature review.	An established set of standards
Benefits	Knowledge sought need not benefit subjects involved in study.	Knowledge that is sought, directly benefits the process/program/system.
Risks/Burdens	May put subjects at risk	No risk, with exception of possible privacy/confidentiality concerns
Data Collection	Systematic or exploratory methods	Systematic data collection limited to aspects of a particular process, program or system.
End Point	Establish certain facts, discover phenomena or broad principles that contribute to public, discipline-based or interdisciplinary body of knowledge.	Improve a specific program/process/system or some specific portion of one.
Testing/Analysis	Describe frequency and importance of factors, inquire about existence and strength of relationships among factors, determine temporal order of factors, establish likelihood of certain outcomes.	Compare the program/process/system to established set of standards
Intended Result	Share findings with individuals associated with the investigation and individuals not associated with the investigation; disseminate in public forums, publications or other media	Share findings with only those individuals associated with the evaluated process/program/system.



Cayuse IRB: Electronic submission system

Dashboard

When you first log in to Cayuse IRB, you will be taken to your **Dashboard**. This screen displays an overview of all the studies you are involved with or that require your attention, and offers a quick way to view and filter studies, submissions, and tasks.

The screenshot shows the Cayuse IRB Dashboard for a user with the role of 'Researcher'. The dashboard is organized into several sections:

- Summary Cards:** Four cards at the top show the status of submissions: In-Draft (9), Awaiting Approval (4), Pre-Review (10), and Under Review (23). A 'New Study' button is located in the top right.
- My Studies:** A table listing studies with their IDs and titles.

Study ID	Title
IRB-FY2015-49	Evaporation of marine layers
IRB-2016-154	Use of compression in wound healing
IRB-2016-151	Social effects of early onset hair loss
IRB-FY2014-87	Sunlight exposure and depression
IRB-2016-148	Efficiency of hydroelectric dams
- My Tasks:** A table listing tasks with their IDs and descriptions.

Task ID	Description
IRB-FY2016-91	Complete Submission
IRB-FY2016-84	View Submission
IRB-FY2016-84	Certify Submission
- Submissions by Type:** A table showing the count of submissions for various types.

Type	Count
Initial	10
Withdrawal	1
Modification	2
Renewal	9
Incident	1
Closure	1
Legacy	5
- Approved Studies:** A table listing approved studies, identical to the 'My Studies' table.
- Studies Expiring in 30 days:** A section indicating 'No Expiring Studies' with a smiley face icon.
- Expired Studies:** A table listing expired studies.

Study ID	Title
IRB-FY2016-3515	Consumption of grass by felines



Working with the IRB: Helpful Hints

- Contact the IRB office first
- Submit your protocol early & include as many details as possible
- Complete the required online CITI training
(*required for all study personnel)
- Any undergraduate & graduate personnel must be added into Cayuse IRB manually by IRB staff before they can be added to a protocol
- If minors will be recruited, parental consent will be required.



Summary

Ultimately, the protection of human subjects in research is the responsibility of the institution, the IRB, the staff, and the researcher.

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