

The Institutional Review Board: What, Who, When, Where, Why, and How

Prepared by
HSU Office of Research and Sponsored Programs

Humboldt State University

Policy for the Protection of Human Research Subjects

- HSU is committed to the protection of the rights of human subjects participating in research.
- HSU is in compliance with California State University Executive Order No. 890.
- HSU is guided by the Code of Federal Regulations, 45 CFR 46.

What Is the Institutional Review Board (IRB)?

- The IRB is comprised of:
 - A committee whose members are appointed by the President for five-year terms
 - Persons from diverse backgrounds
 - Both male and female members
 - At least one member whose primary expertise is in a nonscientific area
 - At least one member who is not affiliated with HSU in any way

Types of IRB Review

- Exempt: requires completion of an application packet for IRB approval (single reviewer)
- Expedited: requires completion of an application packet for IRB approval (single reviewer); topics denote potential risk and/or subjects are from vulnerable populations
- Full: requires completion of an application packet for IRB approval (full board review)

What Policy Applies?

- HSU Policy for Protection of Human Subjects in Research

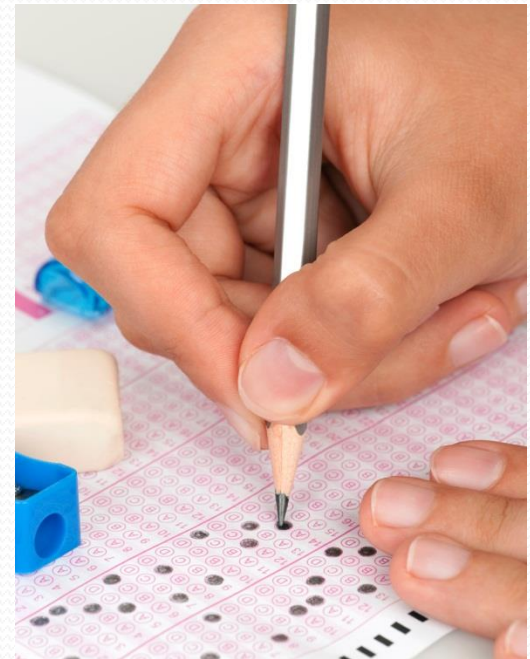


When Does HSU's IRB Policy Apply?

- Research or data collection that involves human subjects and is sponsored by HSU
- Research conducted by or under the direction of HSU employees, auxiliary employees, and/or students (including student/faculty collaborative research) using HSU's time, facilities, resources, and/or students
- Research by students, which must be sponsored by a member of the faculty.

What Is Human Subjects Research?

- Systematic investigation (including research development, testing and evaluation) involving individuals about whom an investigator obtains data through intervention or interaction or obtains identifiable private information



What Is Human Subjects Research?

- All student-conducted research that uses human subjects and that is intended for publication
 - Includes applicable undergraduate independent study projects, graduate projects, theses and pilot studies
- In general, class projects and quality assessment projects do not require IRB review (unless there is a plan to disseminate outside of the classroom).

What Constitutes Human Subject Involvement?

- When human beings are asked to participate physically in an activity or to donate their tissue, organs, fluids and other bodily material
- When information is sought from living human beings directly (as through interview or questionnaire) or indirectly (as through observation) where individual responses are identifiable

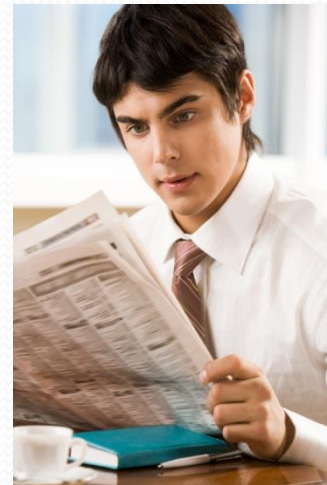


What Constitutes Human Subject Involvement?

- When identifiable information concerning living human beings is asked for from third parties (as through access to files, data banks or other means), or through direct inquiry of third parties concerning the individuals in question

What is Not Human Subject Involvement?

- When an activity uses publicly available data (e.g., newspapers, magazines, journal articles) for analytical purposes that are not identifiable by individual or group and when such data are not proposed for a use that conflicts with the conditions under which the data were originally obtained



What is Not Human Subject Involvement?

- When people are asked to provide information about their organization, profession, or community as a function of their job, profession, or standing in the community. In these situations, information about the participants' feelings, opinions, or understanding is **not** collected.

Does My Project Require IRB Approval?

- If you are unsure, send a detailed description of your proposed project to irb@humboldt.edu.
- Title the submission DETERMINATION OF IRB APPROVAL.

What if My Project is Subject to IRB?

- Once you have determined that your project needs IRB approval, all research personnel, including students, that have direct contact with research participants must complete CITI training.
- For further information, go to the HSU Office of Research, Economic and Community Development website for IRB: <http://www2.humboldt.edu/irb/>
- You will find IRB forms and information on completing training.

How Do I Begin the IRB Process?

- Review the Federal Regulations and HSU's Policy.
- Go to the IRB Home Page and follow the instructions to complete your application.

<http://www2.humboldt.edu/irb/>

Do I Require IRP Approval?

- If your research involves collecting data online from HSU students, staff, and/or faculty, review HSU's Online Survey policy and practice <http://www.humboldt.edu/irp/survey.html> and obtain authorization from the Office of Institutional Research and Planning (IRP), if applicable.

What is the HSU IRB Process?

- Applications are submitted to the IRB Coordinator.
- The Coordinator reviews the applications to make sure the primary required elements are included.
- If there are omissions, the Coordinator contacts the researcher.
- The Coordinator sends the application to the IRB reviewer for content review.

What Is the HSU IRB Process?

- The IRB reviewer returns the application to the Coordinator with a) approval, b) a request for more information, or c) a referral to the IRB for a full board review.
- Once approved, the Coordinator sends an approval letter to the researcher via email.
- The Coordinator tracks all contacts, requests, etc.

IRB Training

- Training is provided through the Collaborative Institutional Training Initiative (CITI).
- Training is free, web-based, and takes a few hours to complete.
- Contact the IRB office (826-5165) for tips on taking the CITI course most efficiently.



What Are We Doing to Improve?

- Revising forms to enable a writable pdf format
- Creating a database with automatic reminders on expiration
- Increasing outreach to faculty and programs through visits to classrooms, etc.
- Soliciting input and advice about desired improvements

What Else Can We Do?

- Communicate better at all levels
- Update guidelines and forms
- Maintain high expectations
- Provide guidance and oversight of student work efforts



Your Help Is Needed

- Inform students, faculty, chairs, and administrators of policy related to human subjects research
- Provide a thorough review of documents for accuracy and compliance prior to submitting to the IRB

In Conclusion...

- We are in this together, with the same goals
- Contact ORSP if you have any questions or concerns
- Help us identify areas in need of improvement

Thank You for Attending



Waiver of Written Consent

- Requirement to obtain written consent from subjects may be waived in certain situations, such as:
 - Subjects are from cultures that utilize oral traditions.
 - Written consent might hinder rapport building in cross-cultural research or oral history recordings.
 - Research uses existing data held by a third party and no identification is possible.

Waiver of Written Consent

- Subject has sought participation in an adequately publicized research activity (e.g., a notice posted on a bulletin board) in which the nature of the risks and benefits are clearly explained.
- Subject is from a class of people able to protect themselves, such as public officials, etc., and is being questioned on matters pertinent to his/her profession.
- Obtaining written consent would be impossible, such as with telephone surveys.

Waiver of Written Consent

- The IRB will review each waiver request individually.
- Requests should be thoroughly explained and include a description of the alternate method of obtaining consent
- If oral consent is planned, the text of the statement must be submitted.