

HUMBOLDT STATE UNIVERSITY

OFFICE OF THE PRESIDENT

**OVERVIEW OF THE
POLICY FOR PROTECTION
OF
HUMAN SUBJECTS IN RESEARCH**

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HUMBOLDT STATE UNIVERSITY
Overview of the Policy for the Protection of Human Subjects in Research
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This is a very brief overview of Human Subjects policy and processes as implemented at Humboldt State University. The complete policy, the policy implementation guidelines, and submission forms can be found at http://www.humboldt.edu/~gradst/Human_Subjects_Form_Page.html

Federal regulations mandate that research which involves gathering information about living human beings must be evaluated by an Institutional Review Board to assure that appropriate measures are being followed to protect the safety and well-being of the human subjects. Virtually all federal agencies subscribe to the “Common Rule,” the Federal Policy for the Protection of Human Subjects. Humboldt State University has additionally provided an Institutional Assurance to the federal government that all research conducted by faculty, staff and students will be reviewed for compliance with federal regulations, whether the research is funded by federal dollars or not. The National Institute of Health and Veterans’ Administration now require that researchers funded by them must submit proof that they have received training in IRB policies. The Department of Health and Human Services is considering this requirement. Many universities now require that anybody who will be involved in research involving human subjects must be certified as trained.

Humboldt State University, with permission from San Diego State University (Human Research Protection Program), provides researchers with training. Researchers can complete the training and the quiz by going to the HSU Moodle site, <http://learn.humboldt.edu/course/view.php?idp=3827>. Researchers submit proof of completion when submitting an IRB proposal to be reviewed. The proof of completion (of training) is effective for three years.

To help faculty, staff, and students know when their activities need to be submitted for IRB review, we provide the following definitions and our local interpretation of them.

Definitions:

Research. A systematic, intentional, formalized plan of investigation that is designed to develop or contribute to generalizable knowledge.

Human subject. A living human being about whom (not necessarily from whom) a researcher obtains information. Data may be obtained through interaction or intervention with the person, or may be information that can be linked specifically to an identifiable individual.

Interacting with a human being does not necessarily make them a “human subject.” Humans providing factual information about organizations or other groups are not “subjects” but if they are providing information about how they perceive or feel about an organization or group they are “subjects.”

Given the ambiguity of the term “generalizable,” the Humboldt IRB has taken the position that any proposed systematic plan of investigation involving human subjects with results which *will or may be disseminated* to audiences should be submitted to the IRB for review. Some examples may help clarify this.

1. Research that faculty, staff, or students might submit for possible conference presentations or publication must be cleared by the IRB.
2. Masters’ thesis or projects must be cleared since, at minimum, they will become available in the library.
3. Undergraduate student research in courses (like senior capstones) and independent projects must be cleared because these projects might be submitted for consideration of awards offered by professional associations or other organizations.

The Humboldt IRB does not require that data gathering activities conducted by students as part of courses in research methods or data analysis be brought before the IRB. We expect instructors of these classes to include principles of human subject protection in these courses. We also strongly recommend that departments offering such courses have one or more faculty trained in IRB policies review the data generating activities, as a protection for the instructor offering the course. Instructors should complete Form 4, Exemption for Course Assignment.

Fundamental Principles:

1. Respect for persons: individuals must be treated as autonomous agents who enter into research voluntarily and with adequate information about the purpose and procedures of the research. Individuals with diminished autonomy (children, prisoners, individuals who are in some way incapacitated) have a right to be protected.
2. Beneficence: researchers are obliged to secure the well-being of their subjects. Possible benefits from participating in the research should be maximized for the individual subjects at the same time possible harms from participating in the research should be minimized for the individual subjects.
3. Justice: risks and benefits of research should be distributed equally across various human groups. The burden of serving as research subjects should not largely fall to certain groups such as the poor or imprisoned while other groups primarily benefit from the results of the research.

There are three categories of research recognized by the federal regulations. Some research is considered “exempt” from the federal regulations to document subjects’ informed consent, some may receive an “expedited” review by the local IRB when subjects will experience no more than minimal risk when participating in the research, and some require a “full board” review due to potential risks to human subjects. Ultimately, **it is the responsibility of the institutional review board to determine what category applies to proposed research.** All proposed research including “exempt” research must be submitted for IRB clearance.

Proposed research involving human subjects must receive IRB approval before data collection or analysis may commence. It is at the point that a researcher formulates a systematic, intentional plan of investigation that the IRB must be involved. This means that information gathered for other purposes may be used for research purposes, but only after IRB review.

All IRB proposals must include the Proposal Submission Check List, Form 1 (Faculty/Staff Cover Letter) or Form 2 (Student Cover Letter), Form 3 (Application Form), or Form 4, if requesting an Exemption for Course Assignment. Additionally, the applicant must submit an abstract, and copies/descriptions of measurement instruments (e.g. experimental dependent measures, survey forms, interview schedules). Expedited and Full Board proposals also require submission of a research protocol and consent forms. The IRB forms are available at http://www.humboldt.edu/~gradst/Human_Subjects_Form_Page.html. Submit an original and one copy to the Office of Research and Graduate Studies, SH 130.

The members of Humboldt State's IRB are able to review "exempt" and "expedited" research proposals year round. Proposals requiring "full board" action are usually only considered during Fall and Spring semesters.

Humboldt's Human Subject policy, the implementation document, and the forms required for submitting a proposal to the IRB are available at http://www.humboldt.edu/~gradst/Human_Subjects_Form_Page.html.

Further information about the Federal guidelines and how to interpret them can be found at <http://ohsr.od.nih.gov/guidelines/belmont.html>, and the official federal language can be accessed at <http://ohrp.osophs.dhhs.gov>