

IMPLEMENTATION OF THE POLICY FOR PROTECTION OF HUMAN SUBJECTS IN RESEARCH

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HUMBOLDT STATE UNIVERSITY

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Note: It generally takes a week for “exempt” and most “expedited” projects to gain approval. It takes longer for a “full board review.”

Introduction

The intention of this packet of materials is to provide the essential definitions for compliance with the Humboldt State University Policy for Protection of Human Subjects in Research. The forms necessary for submission of a research proposal for Institutional Review Board (IRB) evaluation are located on the web at. The full policy is also available at this site.

The fundamental principles underlying the IRB review of proposed research are:

- 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.
- 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.
- Justice: risks and benefits of the research should be distributed equally across various human groups. The burden of serving as research subjects should not largely fall on certain groups such as the poor while other groups primarily benefit from the results of the research.

Humboldt State is committed to the protection of the rights and welfare of human subjects involved with university related research. Subjects will give fully informed consent, will not be exposed to unreasonable risk, and will have their personal privacy respected. Special precautions will be taken to assure the protection of vulnerable populations. Any risks to an individual must be outweighed by benefits to her/him or the importance of the knowledge to be gained, as judged by the primary investigator and by the IRB. The campus policy discusses these commitments, the university committee structure and other issues in greater detail.

Section 1: Defining Research

A wide range of teaching and service activities that HSU professors do is not subject to IRB review. To be research, an activity must constitute a (1) systematic investigation that (2) is designed to develop or contribute to generalizable knowledge. Not all interactions with human beings necessarily make them human subjects. A human subject is a living human being about whom (not necessarily from whom) a researcher obtains information. Data may be obtained through interaction, observation, or intervention with the person, or may be information that can be linked specifically to an identifiable individual. Thus humans providing factual information about organizations or other groups are not “subjects.” If they are providing information about how they perceive or feel about an organization or group as part of an investigator’s research, they are “subjects.” If they are physically engaged in an activity or provide tissue, fluids, or other bodily material for research purposes, they are “human subjects.”

Is the teaching and service that HSU professors do unregulated and un-reviewed; not at all. These non-IRB reviewed activities are subject to appropriate codes of ethical conduct originating from sources other than the HSU Policy for Protection of Human Subjects in Research and Executive Memorandum P 92-7. Examples of such codes are the Codes of Ethics of the American Psychological Association and the

American Sociological Association. All behavior by professors is simultaneously regulated by numerous ethical codes.

The term research is not intended to apply to:

- routine course, workshop, or curriculum development using accepted educational practices sponsored by HSU, including evaluation to determine student /participant satisfaction, attitude change, and/or knowledge gained during the educational experience;
- aid or services provided by professionals to their clients that are consistent with accepted and established practice, and intended only to meet the clients' own personal needs; or services performed strictly for the benefit of the subject, unless they place the subject at risk.

Examples:

- Classroom instruction is a service and does not require review.
- A training program does not constitute human subjects research if no data are collected.
- Administrative surveys, questionnaires, and interviews not supported by federal funds and designed for use in the internal management and operation of the University do not constitute Research within the meaning of this policy if the information or conclusion are not intended for scholarly publication or for dissemination to persons outside the administrative organization of the University.
- Classroom curriculum projects, workshop evaluations, and administrative review projects need not be reviewed by the IRB if they are not research, results will not be distributed outside the classroom or institutional setting, or are used to evaluate or review a program in order to build a better program.
- If the library surveys its patrons with no other purpose than to evaluate its services, it is not research.

Given the ambiguity of the term “generalizable,” the Humboldt IRB takes the position that any proposed systematic plan of investigation involving human subjects, the results of which will or may be disseminated to audiences beyond HSU classrooms and/or administrative units must be submitted to the IRB for review. Some examples may help clarify this.

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

Many people think it is the activity itself that constitutes research (i.e. all surveys are research). This is not true. It is the purpose of the activity and the eventual use of the information obtained that ultimately makes the difference between research and everything else.

Proposed research (as defined above) involving human subjects (as defined above) must receive IRB approval before the investigator can begin undertaking data collection. Does this mean that data previously collected to evaluate, for example, workshop presentations, curricular innovation, or library patron satisfaction cannot be subsequently used for a research project; not at all. When a faculty, staff, or student forms the intent to use this type of data for a systematic, intentional investigation for the purposes of dissemination external to HSU, an IRB proposal should be submitted at that point to receive approval for use of this data for the purposes of research. If you have questions about this determination, please contact the IRB Chair or a committee member.

Section 2: Responsibilities of Individuals and Groups

The principal investigator has the primary responsibility to: (1) protect human subjects as required by law and campus policy, and (2) to prepare and document reports of the research sufficient to allow review and approval by the IRB, appropriate administrator (Dean for Research and Graduate Studies), and by any authorized governmental review agency.

When the principal investigator is a student, the supervising faculty member must assure that all regulations and processes are followed and that the necessary forms are submitted to the IRB. The faculty member's signature must be present on the form(s) and when appropriate, all faculty members of a supervising committee (as for master's students) should sign the form.

The chair and/or vice-chair of the IRB have the following responsibilities:

- Chair the committee.
- Review projects submitted to assure correct classification and adequate documentation. Appropriate material should be made available on a periodic basis to the committee as a whole to allow discussion of the principles and practices for project classification, review and approval. A log or file of such projects would meet this requirement and would allow for periodic review.
- Assure that all necessary information is available to the committee in cases where a "full review" is required.
- Assist principle investigators in preparing documentation for IRB proposals as appropriate.

The appropriate administrator or designee, as appointed by the President:

- Attends IRB meetings as needed.
- Periodically reviews approvals in all categories.
- Recommends improvements in campus policy or procedures.
- Supervises staff assigned to support the committee. The staff member will maintain records to document university compliance with legal requirements and CSU and university policies.
- Receives appeals by primary investigators or departments if they wish to contest a university committee decision not to approve a research project because risks are judged to outweigh benefits.
- Identifies and recommends professors as chair of the IRB to the President.

Section 3: Determination of Category of Research

There are three categories of research recognized by the federal regulations. Some research is considered "exempt," some "expedited," and some requires "full board" review. "Exempt" research is activity that does not require documentation of written informed consent by research subjects. "Expedited" research involves no more than minimal risk to the research subjects. Determination of minimal risk involves evaluating the kinds of ordinary risks the subjects would encounter in their daily lives. What might be minimal risk for some subjects (student athletes) might be much more than minimal risk for other subjects (senior citizens). Research that poses more than minimal risk to the subjects requires "Full Board" review. Please note that all research proposals, regardless of the category the investigator believes the research fits, must be reviewed by the IRB. It is ultimately the IRB that determines whether the proposal falls within the "exempt," "expedited," or "full board" review category.

Definition of "exempt" research: Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

- a) Research on regular and special education instructional strategies, or
 - b) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
- a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b) Any disclosure of the human subjects' response outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
 - c) N. B. If both 2a and 2b apply, your research is not exempt.
- 3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:
- a) Human subjects are elected or appointed public officials or candidates for public office; or
 - b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- 5) Research and demonstration projects which are conducted by or subject to the approval of (FEDERAL) department or agency heads, and which are designed to study, evaluate, or otherwise examine: a) Public benefit or service programs;
- b) Procedures for obtaining benefits or services under those programs;
 - c) Possible changes in or alternatives to those programs or procedures;
 - d) Possible changes in methods or levels of payment for benefits or services under those programs.
- 6) Taste and food quality evaluation and consumer acceptance studies,
- a) If wholesome foods without additives are consumed, or
 - b) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Requests for Exempt Status for Survey Research

Please note that not all research which uses only surveys is “exempt.” To be granted an exemption, your survey must meet the following criteria:

- Subjects must all be 18 or over;
- Subjects’ responses must be made anonymously, or the
- Information requested must place subjects at no risk if disclosed.

Certain topics require full board review, even if the method of obtaining data is an anonymous survey. These include questions on drug and alcohol use, criminal activities, sexual activities or preferences, AIDS testing and results, suicide attitudes, divorce and its effects on psychological well-being, instances of child or sexual abuse, and eating disorders.

Surveys involving children (persons under 18 years old who are neither emancipated nor married) cannot be granted exemptions. Surveys involving children require parental consent and full-board review.

A survey is anonymous only if no one, including the researcher, can know which subject made which

response. Risks to be considered include risk of criminal or civil liability, damage to subject's financial standing, employability, or reputation.

Use of some or all of the following strategies will help to assure that your survey is exempt:

- a) Include information on the top of the survey (or in oral instructions for a phone survey) indicating that it is research, subject participation is voluntary, people under 18 years of age cannot participate in the survey, and instruct respondents to not write their name anywhere on the survey, or to not tell the researcher their name.
- b) Instruct the subjects to return the survey to a mail address, drop box, or other location where their responses will be mixed with those of other subjects before they are reviewed.
- c) Use only random phone dialing methods or randomly generated lists of phone numbers rather than directories to administer a phone survey.
- d) Ask only questions on your survey which place subjects at no risk.

If your request for exemption is denied, you may revise your research proposal and resubmit your request for an exemption.

Section 4: Brief Instructions for Obtaining Approval for Research

Researchers are required to submit all proposals for research involving human subjects to the Institutional Review Board (IRB, care of the Dean of Research and Graduate Studies). Approval must be formally conveyed in writing before the research may begin. Research in which a student is the principal investigator (e.g., a thesis) must first be submitted to the appropriate department for review. The graduate thesis committee may serve this purpose. All other proposals for research are submitted directly to the IRB.

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 complete the training and quiz on Moodle. A maximum of six attempts are permitted with a delay of two days between each attempt. Researchers submit proof of completion when submitting an IRB proposal to be reviewed. The proof of completion of training is effective for three years.

For research that the investigator believes fits the "exempt" category, the IRB requires two (2) forms for each new study involving human subjects: a faculty/staff or student cover letter, (Form 1 or Form 2, as appropriate) and Form 3, the application form. Additionally, the applicant must submit the abstract and measurement instruments.

For research that the investigator believes should receive "expedited" or "full board" review, the IRB requires two (2) documents for each new study involving human subjects: a faculty/staff or student cover letter (Form 1 or Form 2, as appropriate), and Form 3, the application form. An abstract, the protocol, measurement instruments, and the consent form must be attached. The protocol should be prepared using the headings indicated in the list which follows. Text must be double-spaced, and all pages numbered.

The application form is self-explanatory. Be sure to fill in all categories, placing N/A where appropriate.

The abstract is a brief summary of the proposed study which will include all the pertinent points of the research, and will highlight the potential risks, the potential benefits to the subjects, and risk management procedures. It should consist of the following:

1. Title of project and principal investigator's name;
2. One paragraph summarizing the introduction;
3. One paragraph summarizing the methods section;
4. One paragraph summarizing the discussion section, indicating the potential benefits of the research;

5. A discussion of potential risks and how they will be managed. The abstract generally should not exceed two pages double-spaced.

The protocol is a statement of the researchers' responsibilities toward the human subjects involved in his/her research and contains the following information:

1. Purpose and Background
2. Methods Section
3. Subjects
4. Potential Benefits
5. Potential Risks
6. Management of Risk
7. Personnel
8. Other

The Board usually needs to know something about how the data will be analyzed and what the significance of various results will be in order to evaluate the potential benefit of the research. This should be covered in sections a, b and d.

The consent form must be in non-scientific language, use second person (e.g. "As a participant in this research you will be asked..." and include the following:

1. Procedures, including time involved and locale and names of researchers administering procedures;
2. Purpose of research (including larger social purpose, if appropriate);
3. Statement of risks and/or discomforts, how these have been minimized by the researchers, and how the subject may contribute to minimizing risks as well;
4. Statement of potential benefits for the subjects;
5. Where applicable, statement of alternative treatments, their risks and benefits;
6. Assurance of withdrawal without jeopardy and that participation is voluntary;
7. Assurance of investigator's readiness to answer questions (provide contact information; phone number, email);
8. Contact information for individual "supervising" the research (faculty advisor for student projects, the Dean for Research and Graduate Studies for faculty/staff research);
9. Where applicable, terms of compensation;
10. Where applicable, provision for guardian's consent;
11. Where applicable, provision for consultation with independent physician, or attending physician's signature;
12. Signature lines for subject and/or guardians; and the date. Samples of informed consents are available online at: www.humboldt.edu/human_subjects.

Conditions under which written informed consent may be waived are outlined in the "Policy for the Protection of Human Subjects in Research" available online at: www.humboldt.edu/human_subjects.

Section 5: The Appeals Procedure

The IRB's intent is to work with researchers until all human subjects' problems have been solved and the project has been approved for implementation. If the applicant believes that a proposal has been disapproved because of incorrect, unfair, or improper evaluation by the IRB, he/she may appeal to the IRB Chair, who shall request a reconsideration of the proposal by the IRB.

The appeals procedure is as follows:

Adverse final decisions on specific projects can be appealed by the researcher(s) and department(s).

The researcher(s) must show cause in writing or at a designated hearing as to why the IRB decisions should be reversed within 14 working days after the receipt of notification of negative decision.

An appeals committee of three (or more) IRB members will be appointed by the chairperson to conduct any special appeals review. At the request of the researcher, an outside reviewer may be added to the subcommittee.

The appeals committee may take the following action:

1. Return the proposal to the total IRB for reconsideration, or
2. Affirm the original decision of the IRB denying approval to the appealing researcher and/or department.

Arbitration

Any matters requiring arbitration between the IRB and a principal investigator or questions not resolved by the IRB, will be referred to the appropriate administrative officer or administrative office. The administrative officer or the Board and the principal investigator, will seek resolution of the differences. They will report their findings to the Board and the principal investigator, after which the IRB will meet again to reconsider the matter and render a decision, in accordance with Federal policy. In no instance may any official of the institution overrule an IRB decision for disapproval.

An avenue open to the researcher is to modify objectionable items with his or her research to conform to IRB and Uniform Federal Policy. Although other organizations of the institution may review the proposal, those officials may not approve the research if it has not been approved by the IRB.

Section 6: Extensions, Modifications and Reporting Significant Deviations from Approved Protocols

Approvals of research protocols, regardless of the category of research are approved for one year from the date of approval. If your research process will take longer than one year, submit another application form, indicating that you wish to extend your research.

If you discover that you need to change the way you are conducting your research after you have received an approval from the IRB, you will need to seek approval for modification of your research process. Reasons for requesting approval of modifications include proposed changes in: recruitment of subjects, subject characteristics, compensation of subjects, investigatory methods including changes in measurement strategies, benefits and/or risks for subjects, personnel involved in the research, etc. Changing any element of the proposed research that was evaluated and approved by the IRB requires submission of request for modification. Only those aspects of the research that you are proposing to change need to be addressed in the application to modify. You must suspend (stop) your research until you receive IRB approval of the proposed modifications.