Executive Memorandum

POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

The Humboldt State University (HSU) Institutional Review Board (IRB) exists to ensure the protection of the rights and welfare of human subjects recruited to participate in research. All individuals listed on an HSU IRB application are required to take an online training that provides essential background information on policies and principles of human subjects protection (http://www.humboldt.edu/hsuf/irbciti.php). HSU is in compliance with California State University Executive Order No. 890 and HSU's Federalwide Assurance (FWA00001093), as approved by the Office of Human Research Protection (OHRP) of the United States Department of Health & Human Services (DHHS). The HSU Institutional Review Board for the Protection of Human Subjects in Research (IRB) has the authority and responsibility to 1) review proposed data collection and research efforts involving human subjects, and 2) maintain records and written procedures in accordance with institutional, local, state, tribal and federal regulations. HSU adheres to local, state and federal regulations governing the protection of human subjects in research. Detailed procedures are articulated in the "HSU IRB Procedure Manual," and are available on the Human Subjects in Research webpage (http://www.humboldt.edu/hsuf/irb.php).

Activities Covered by This Policy:

This policy applies to data collection and research efforts involving human subjects:

- conducted at HSU;
- using HSU facilities;
- by HSU employees (faculty and staff), students, or other persons affiliated with HSU;
- using HSU employees or students as subjects; or
- under the auspices of the HSU Sponsored Programs Foundation or other HSU auxiliaries.

- *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- *Generalizable knowledge* refers to information or data that are analyzed, from which conclusions are drawn, and then are disseminated outside of a classroom or University unit, for example through publication, presentation, or on the internet.
- *Data collection* refers to the collection and compilation of information about or from human subjects. Sources of data include existing records, surveys, interviews, websites, databases, focus group discussions, forums, and similar sources of data.
- *Human subject* means a living individual about whom or from whom an investigator collecting information or conducting research obtains: 1) data through intervention or interaction with the individual; or 2) identifiable private information.

This policy does not cover classroom assignments provided that all data collection and dissemination activities for the assignment are restricted to that classroom. The IRB encourages inquiries from University affiliates regarding the applicability of this policy to their projects (contact information is provided on the IRB website).

Procedures for Review:

Any collection of data through intervention or interaction with a human subject, or collection of private information about a human subject covered by this policy will be reviewed by the HSU IRB. The HSU IRB will review and have the sole authority to approve or disapprove all activities covered

by this policy, including new applications and modifications or renewals of existing protocols. No other entity or individual at HSU may approve data collection or research that involves human subjects covered by this policy. Appeals of an IRB decision should be referred to the IRB Institutional Official at HSU within 10 working days of the decision.

Student Responsibilities:

Students involved in data collection and research activities must be under the guidance, supervision and ultimate responsibility of a HSU faculty or staff member. Students are responsible for:

- ensuring continuous enrollment during the data collection period;
- ensuring the quality and accuracy of the written materials included in the *Application for Review*;
- the conduct of the proposed protocol;
- compliance with all federal, state, and local regulations, as well as HSU policies regarding the protection of human subjects in research;
- providing all informed consent documentation for participants involved in the student's data collection and research efforts to their faculty or staff supervisor for retention;
- reporting to faculty or staff supervisor immediately if there are any adverse events and/or unanticipated problems involving risks to subjects or others; and
- adhering to and complying with any and all stipulations imposed by the faculty or staff member supervising their data collection and research efforts and by the HSU IRB.

All student IRB applications must be submitted electronically by an HSU faculty or staff member, who is supervising the student's work.

Faculty and Staff Responsibilities:

All student data collection and research efforts, including theses and projects, covered by this policy must be supervised by a faculty or staff member, who is ultimately responsible for the protection of human subjects in research. Supervising faculty or staff members are responsible for ensuring the appropriate training and conduct of students. It is recommended that supervising faculty or staff members verify that student investigators maintain continuous enrollment (minimum of one unit of academic credit) during data collection activities.

The faculty or staff primary investigator, or the faculty or staff member supervising student data collection and research efforts is responsible for:

- ensuring the quality and accuracy of the written materials included in an application submitted to the IRB;
- ensuring human subjects in research training for all personnel who may interact with human subjects or have access to subjects' information or responses;
- supervising the conduct of protocols under their direction;
- ensuring compliance with all federal, state and local regulations, as well as HSU policies regarding the protection of human subjects in research;
- adhering to any stipulations imposed by the HSU IRB;
- retaining all data, including informed consent documentation for participants, in accordance with institutional, local, state and federal regulations; and
- reporting to the HSU IRB immediately if there are any adverse events and/or unanticipated problems involving risks to subjects or others.

All applications must be submitted to the IRB electronically by an HSU faculty or staff member. By submitting an application, the faculty or staff member acknowledges and accepts the responsibilities listed above and on the electronic application.

Responsibilities of the HSU IRB:

The HSU IRB will:

- establish a policy for the protection of the rights and welfare of human subjects in research in which the institution is engaged;
- facilitate the appointment of members to the IRB in compliance with the federal and institutional regulations;
- prepare and maintain adequate documentation of IRB activities in accordance with institutional, local, state and federal regulations;
- develop and maintain a procedure for adequate training of personnel;
- develop and maintain a process for allowing research by non-HSU affiliates involving HSU personnel and/or facilities; and
- review this policy periodically for consistency with applicable laws and regulations, including but not limited to, Title 45, Code of Federal Regulations, Part 46 and CSU Executive Order No. 890.

The HSU IRB will provide the President, through the Dean for Research & Sponsored Programs, with a yearly report (due within 2 weeks of the close of the fiscal year), consisting of, but not limited to: the number and type of proposals reviewed, committee membership, any adverse events or unanticipated problems involving risks to subjects or others, and any changes in federal, state, or local regulations.

University Responsibilities:

The University will:

- maintain a statement of principles governing the University in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the University, regardless of whether the research is subject to Federal regulations;
- maintain one or more IRBs established in accordance with the requirements of the Code of Federal Regulation (45 CFR 46), appointed by the President or designee, to ensure adequate review of protocols involving human subjects;
- provide the IRB with meeting space and sufficient staff to support the IRB's review and record keeping duties;
- maintain a Federalwide Assurance approved by the Office of Human Research Protections;
- ensure that approved protocols are followed; and
- provide administrative and fiscal support, as needed, to the IRB for training of IRB members and other personnel.

The Dean for Research and Sponsored Programs is authorized to act on behalf of the University to maintain registration of HSU's Federalwide Assurance. The President or designee is authorized to implement regulations required by funding and regulatory agencies for the protection of human subjects in research. Questions regarding this policy should be directed to the Dean for Research & Sponsored Programs or Chair of the IRB (contact information here).

Procedures for Application or Registration Submission, Review, Modification, Renewal, and Expiration:

The HSU IRB webpage and the IRB application form contain additional procedural information.

Submitting a new IRB application:
IRB applications must be submitted online through the HSU IRB webpage. Only the primary investigator or faculty or staff supervisor may submit the application. Every individual listed as personnel on the IRB application must complete the required human subjects training course, available through the HSU IRB webpage, before the application will be accepted for review. Certification of completion of the human subjects training course expires after 3 years and the course must be repeated for recertification. Supporting documents that should be uploaded with new IRB applications may include: certification of completion of the human subjects training course, consent forms, assent forms, participant informational forms, survey or interview questions, documentation of permission to recruit participants from or to use outside institutional facilities, debriefing narratives, or other documents.

Submitting a new IRB registration:
Registration may be used instead of a full application only in cases where the registration is used for (a) grant submissions, where no actual human subjects research will occur unless the grant is funded, in which case a full IRB application is still submitted and approved before any research activities begin, or (b) research that already has an Exempt designation from the IRB of an outside institution, in which case documentation of IRB approval from the outside institution must be submitted to the HSU IRB.

Review of IRB application and registration requests:
The HSU IRB will determine which of its members will review any particular application or registration request. Initial reviews should be completed within 10 green days. Applicants will either receive approval or requests for revisions and resubmission of the application. In most cases communication between the IRB and applicants or approved protocol holders (primary investigator and supervisor) is done through email.

Modifications to projects with active IRB approval:
Applicants must notify the HSU IRB through email of any changes to project personnel or procedure. These changes must be approved by the IRB before they are implemented.

Terms of IRB approval: Renewal and Expiration
IRB applications are approved for one (1) year unless otherwise specified. Data collection or other activity involving direct interaction with human subjects may only proceed during the period of approval. Renewal is the responsibility of the primary investigators and faculty or staff supervisors. The IRB will make every effort to email investigators with notices of expiration one (1) month before expiration of an approved IRB and upon expiration. However, lack of receipt of such a notice cannot be used to justify allowing an expired IRB application to be renewed. Projects with current IRB approval may be renewed for 1 year. **Expired projects may not be renewed; retroactive approval is not allowed per federal policy.**