

HUMBOLDT STATE UNIVERSITY

OFFICE OF THE PRESIDENT

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

SEPTEMBER 2007

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1.0 INTRODUCTION

Humboldt State University is committed to promote, encourage, and facilitate academic and clinical research. The purpose of this policy is both to protect the rights and well being of human subjects of research and to support the human subjects research efforts of Humboldt State University faculty and students. This policy encourages recognition of the basic ethical principles for the use of human subjects, respect for persons, beneficence, and justice. Compliance with this policy provides protections for human subjects as mandated by Title 45 of the Code of Federal Regulations, Part 46, (45 CFR 46) and promulgated by the Federal Office for Human Research Protections at the U.S. Department of Health & Human Services, <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.103>

This document constitutes a statement of principles governing Humboldt State University in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulations, as required by and in compliance with Federal Policy for the Protection of Human Subjects (CFR.46.103 (b) (1)).

1.1 GOVERNING DOCUMENTS

Humboldt State University Executive Memorandum P 98-3 is the campus document that addresses human subjects in research. References cited in this document, such as CFR 46.103 (b) (1), refer to Uniform Federal Policy for the Protection of Human Subjects, presented without CFR and part number in the Federal Register, Vol. 661, No. 219 Tuesday, November 13, 2001. This Uniform Federal Policy substitutes for: 7 CFR Part 1c (Department of Agriculture); 10 CFR Part 745 (Department of Energy); 14 CFR Part 1230 (National Aeronautics and Space Administration); 15 CFR Part 27 (Department of Commerce); 16 CFR Part 1028 (Consumer Product Safety Commission); 22 CFR Part 225 (International Development Cooperation Agency, Agency for International Development); 24 CFR Part 60 (Department of Housing and Urban Development); 28 CFR Part 46 (of Justice); 32 CFR Part 219 (Department of Defense); 34 CFR Part 97 (Department of Education); 38 CFR Part 16 (Department of Veterans Affairs); 40 CFR Part 46 (Environmental Protection Agency); 45 CFR Part 46 (Department of Health and Human Services); 45 CFR Part 690 (National Science Foundation); and 49 CFR Part 11 (Department of Transportation).

1.2 THE BELMONT PRINCIPLES

The use of human subjects in research is extremely important to the development of new knowledge in many areas. However, careful attention must be given to questions of ethics and human dignity whenever human subjects participate in research. In 1978, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research developed broad ethical principles to provide a basis on which specific rules could be developed.

These principles are discussed in *The Belmont Report*. Three basic principles are relevant to the ethics of research involving human subjects:

Respect for Persons: Respect for persons incorporates two basic ethical tenets: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated. In most cases of research involving human subjects, respect for persons demands that subjects enter the research voluntarily and on the basis of adequate information about the research situation and possible consequences.

Beneficence: Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. Two general rules have been formulated as complementary expressions of beneficent actions in this sense. First, do not harm. Second, maximize possible benefits and minimize possible harms. Learning what will, in fact, benefit may require exposing persons to risk. The problem posed by these imperatives is how to decide when it is justifiable to seek certain benefits, despite the risks involved, and when the possible benefits should be foregone because of the risks.

The obligations of beneficence affect investigators because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risks that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of medical, psychotherapeutic, and social procedures.

Justice: Who ought to receive the benefits of research and bear its burdens? This is a question of justice - in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. The selection of research subjects needs to be scrutinized in order to determine whether some groups (e.g., welfare clients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Especially when research supported by public funds leads to the development of therapeutic devices and procedures, justice demands that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

1.3 APPLICATION OF THIS POLICY

The Uniform Federal Policy for the Protection of Human Subjects requires each institution engaged in research to have a written assurance of compliance that includes a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. Although the federal government (CFR.103.(b)(1)) does not regulate research with human subjects that it does not fund, it requires that institutions that receive funding for any human subjects research to be responsible for regulating all human subjects research conducted at or by the institution.

All research projects involving human subjects require prior review and formal approval by an Institutional Review Board. The purpose of this review is to determine whether subjects are at risk, that potential risks are minimized as much as possible, whether the potential benefits of the research outweigh the risks, that adequate provision has been made to obtain informed consent, and that participation is voluntary.

Some projects assigned to students in a class may have a research component or constitute training in research methodology. If such projects contribute to general knowledge (e.g., through publication or dissemination of the findings), they are subject to the regulations and must undergo review. The committee will not give post facto approval.

Classroom projects that are exclusively for instructional purposes need not undergo review by the IRB; however, instructors and students are encouraged to follow federal and university regulations when designing and conducting class projects with human participants.

Humboldt State University recognizes its basic responsibility to ensure the protection of human subjects. The University has adopted this policy applicable to all research involving human subjects that is conducted at or sponsored by the University.

1.4 ASSURING COMPLIANCE

In accordance with the Federal Policy on the Protection of Human Subjects (DHHS Policy 45 CFR Part 46, Code of Federal Regulations Common Rule, Federal Policy for the Protection of Human Subjects, rev. November 13, 2001 implementing Public Law 93-348, July 12, 1974) establishing institutional review boards and an ethics guidance program, Humboldt State University assumes the responsibility for the protection of the rights and welfare of human subjects who participate in research and other activity projects conducted by, or under the supervision of faculty, staff, or students, hereinafter called **researchers**.

To conduct this responsibility effectively, the University has a Committee for the Protection of Human Subjects/Institutional Review Board competent to review research, training, and other activity protocols involving human subjects and to evaluate both risk and protection against risk for those subjects. It is the function of the IRB to (1) determine and certify that all projects

reviewed by the IRB conform to the regulations and policies set by DHHS regarding the health, welfare, safety, rights and privileges of human subjects; and (2) assist the investigator in complying with DHHS regulations in a way that permits accomplishment of the research activity.

1.5 ALL RESEARCHERS MUST:

- Adhere to the principles of Respect for Persons, Beneficence, and Justice embodied in the *Belmont Report*.
- Adhere to the policies and procedures set forth in the University's *Policy for Protection of Human Subjects in Research*.
- Demonstrate knowledge of the principles and processes of ethical research involving human subjects by submitting a certificate of completion of the human subjects tutorial at Humboldt's Moodle page; <http://learn.humboldt.edu/course/view.php?id=3827> when submitting a proposal to HSU/IRB. The certificate is valid for 3 years.
- Make sure that the decision to participate in research governed by this policy meets the **standards of informed consent**. The decision must be: (a) voluntary - it must occur as the result of free choice, without compulsion or obligation; (b) based on full disclosure of the information needed to make an informed decision about whether or not to participate; © based on the subject's comprehension of the information provided. (d) If children are involved as subjects and are capable of assent, normally their assent to participate must be solicited in addition to the permission of their parents.
- Make sure that the selection of research subjects is fair. Subjects should not be selected for potentially beneficial research on the basis of favoritism, nor should risky research be targeted to subjects who are less powerful.
- Make sure that the procedures for recruiting subjects protect their privacy and be reasonable in terms of their condition or circumstances. No coercion, explicit or implicit, should be used to obtain or maintain cooperation. Any payment made to subjects should not be so large as to constitute excessive inducement for participation. When access to subjects is gained through cooperating institutions or individuals, the subject will be afforded the level of protection required by this document.
- Make sure that risks to subjects are minimized and that they are justified by the anticipated benefits to the subject or society.
- Make sure that adequate provision is made to protect the privacy of subjects and to maintain the confidentiality of identifiable information.

- Assure that approval for conducting research with human subjects is obtained prior to any involvement of subjects. All such research must either be reviewed or designated as exempt from this policy by the IRB. All approved projects must be periodically reevaluated.

This policy does not apply to routine courses, workshops, or curriculum development using accepted educational practices sponsored by Humboldt State University, unless the activity meets the definition of research in Section 5 of this document.

2.0 DEFINITIONS

A **human subject** is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (CFR 102(f)).

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) to be of concern in research involving human subjects.

People **not considered to be subjects** are individuals receiving services that are not experimental and which are intended to benefit only the recipient of the service; such services include most therapeutic treatments, counseling, and academic instruction. The definition of "**subjects**" excludes all accepted and established service relationships, students to instructors, and other clients to professionals in which the student, or client is receiving aid or services consistent with accepted and established practice, that is intended only to meet his/her own personal needs. The professional-client relationship has the welfare of the client as the primary objective, whereas the investigator-subject relationship has the discovery of new knowledge as its primary objective. The normal employer-employee relationship is also excluded from the definition of subject. Payment of research subjects for their time as participants does not alter their status as subjects and does not change the relationship to one of employer-employee.

The rights of some subjects require special attention. These include: (1) children, because of their vulnerability, diminished autonomy, and incomplete understanding (in California, most anyone under the age of 18 is not legally able to give consent for research participation), (2) subjects with limited civil freedom, such as prisoners and persons subject to military discipline (in California, prisoners may be research subjects only under very limited circumstances), (3) people with limited capacities or mental disabilities, such as the mentally retarded or the

mentally ill, and (4) pregnant women and the viable fetus, both in utero and ex utero.

IRB means Institutional Review Board.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at HSU within the constraints set forth by the IRB, HSU, and Federal Requirements.

3.0 INSTITUTIONAL REVIEW BOARD

Campus policies and federal requirements regarding research with human subjects are implemented by the Institutional Review Board Committee for the Protection of Human Subjects in Research (IRB) and by the appropriate administrative officer, as appointed by the President.

3.1 IRB CHARGE

The Institutional Review Board is appointed to review research involving human subjects for compliance with applicable federal and state regulations.

3.2 IRB MEMBERSHIP

The HSU IRB includes a Chair elected from the IRB membership by the Committee, and consists of at least six additional members belonging to the university community and one from outside the university. The membership shall include:

- At least one faculty member from each college, chosen to assure both scientific and non-scientific personnel are represented, and one person from Student Affairs to assure that the special characteristics and vulnerabilities of students as research subjects are represented in the knowledge and experience of the committee;
- At least one person qualified to assess each of the following risks: physical (medical), psychological, and social;
- Ethnic diversity and a balanced representation by gender;
- At least one person qualified to assess the validity of experimental design such that the benefits of the research may be adequately assessed;
- At least one member who is not otherwise affiliated with the university; and additional members as necessary to provide adequate attention to special expertise or to the risks of certain research subject populations.

Members will be appointed by the President to serve overlapping 5-year terms.

4.0 SCOPE OF THE REVIEW

The **investigator** is an employee of HSU and is responsible for ensuring that his/her work is conducted in full compliance with all applicable laws, regulations, guidelines, and policies. It is his/her responsibility to refer to the Compliance sections of the Human Subjects Policy on any questions related to compliance or to seek clarification from the IRB.

The **department chair** has responsibilities related to all researchers in his/her unit and/or using facilities charged to the department. It is his/her responsibility to be knowledgeable concerning all relevant aspects of compliance requirements; to ensure that all activities conducted in the department meet with compliance requirements; and to consult with the IRB Chair on any questions related to compliance.

The University meets its responsibilities with respect to complying with applicable laws, regulations, guidelines, and policies. Among these responsibilities are:

- Developing and maintaining a coordinated system of compliance that includes activity review and approval, monitoring, reporting, and enforcement;
- Developing and maintaining a system of auditable files and information for the benefit of HSU, units, and external oversight;
- Providing administrative and consultation services for offices, departments, review bodies and individuals to assist the process of establishing compliance;
- Providing educational services to faculty, staff, and students so that they can better meet compliance requirements;
- Coordinating activities with other units of HSU so that the institution can meet its obligations in the most uniform, effective, and efficient way possible;
- Providing a communications link between agencies issuing compliance requirements and HSU personnel; and
- Submitting assurances, reports and/or other required communications to the appropriate federal and state agencies.
- Humboldt State University affiliated investigators are afforded the normal legal protection by the University, provided their activities have IRB approval and if they are working within the scope of their employment or University association. It is important to recognize that unless these conditions have been met, the University will not be in a position to protect HSU affiliated investigators performing research with human subjects.

4.1 WHOSE RESEARCH MUST BE REVIEWED?

Human subject research conducted and/or sponsored by the University includes that conducted and/or sponsored by University employees, auxiliary employees, and/or students (including student/faculty collaborative research). All studies that utilize Humboldt State University time, facilities, resources, students, faculty, or personnel must be reviewed.

Researchers affiliated with other institutions wishing to use Humboldt State University subjects or work in any capacity under the auspices of the university, must submit a copy of their institution's federal assurance of the protection of human subjects, and documentation of the favorable review of their proposal by the IRB of their own institution, as well as the documentation required by this policy.

4.2 EXTRAMURAL SUPPORT

Researchers requesting extramural support and planning to perform activities involving human subjects under the auspices of the University are required to submit an application for funds through the office of Sponsored Programs Foundation. All extramural research support requests involving human subjects should be submitted to the IRB a reasonable time in advance of deadline, receipt or submission dates specified by the operating agencies. Completed IRB review can under no circumstances be expected in less than 10 working days from receipt of a correctly completed application.

If external funding is requested, the proposal should be submitted to the Institutional Review Board in time to complete the review process and have approval before submission of the proposal; otherwise, if it is not a sponsored project, the proposal should be submitted in time to complete the review before the start date of the research activity that involves the use of humans.

4.3 COLLABORATIVE RESEARCH

Collaborative research (student/faculty), where the faculty member is considered the principal investigator, must be submitted through the channels described below under "application procedures."

4.4 STUDENT RESEARCH ACTIVITIES

For the purposes of this policy, independent student research is not recognized nor is it sanctioned. While the original concept may have come from a student, all student-initiated research involving human subjects must be supervised by a faculty or staff member to assure that human subjects are protected. For thesis research, the signature of the faculty advisor is required. For student research other than thesis, a faculty supervisor's signature is required and the student must be currently enrolled at Humboldt State University during that period of the project when

human subjects are involved. The faculty signature on student research attests that the research procedures comply with federal and university policies with regard to the protection of human

subjects. The sponsor is expected to monitor the research to ensure that the sponsoring faculty are responsible for informing student investigators of human subject procedures and that the approved protocol with human subjects is followed. Sponsoring faculty are responsible for informing student investigators of human subject procedures.

5.0 RESEARCH

5.1 RESEARCH AS FEDERALLY DEFINED

HSU will review biomedical and behavioral research involving human subjects conducted at or sponsored by the University in order to protect the rights of human subjects of such research. Activities which are not research but which nevertheless involve people, are not covered by this policy, but rather by other appropriate codes of conduct. Research is defined by the Uniform Federal Policy (CFR 102 (d)) as: *a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.*

As used in this document, the word research is defined as any systematic gathering and analysis of information, usually made under conditions determined by the investigator, that aims to test a hypothesis, to discover some unknown principle, or effect, or to re-examine some known or suggested principle. The term research includes: (a) studies in which any substance or stimulus is administered to a subject by any means; (b) studies that involve changes in physical or psychological state or environment or major changes in diet; (c) interviews, surveys, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups; and (d) studies of existing public or privately held records where the identity of individuals is known. Activities that meet this definition constitute research even if they are supported or funded under a program that serves other purposes.

The term research is not intended to apply to:

- Routine course, workshop, or curriculum development using accepted educational practices sponsored by Humboldt State University, including evaluation to determine participant satisfaction, attitude change, and/or knowledge gain during the educational experience; or to
- 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.

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 conclusions of the surveys are not intended for scholarly publication or for dissemination to persons outside the administrative organization of the University. A survey which is not research need not be submitted to the IRB

for review. However, administrative personnel are encouraged to seek review by IRB in circumstances where there is potential in the future for scholarly publication or dissemination outside the administrative organization of the University. When the survey involves information of a sensitive personal nature it must be submitted for IRB review.

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 however, the results of the project will be published or otherwise distributed, the project must be reviewed by the IRB. If in doubt have the project reviewed.

Undergraduate and graduate students may be involved in behavioral research using human subjects. There is a wide range in types of student research that occur, everything from course related research exercises to master's thesis. What is the responsibility of the Committee for the Protection of Human Subjects in Research? Departments offer courses that require students to undertake small projects in which other people are interviewed, observed, or otherwise serve as human subjects. The purpose of these course projects is to provide students a closer view of social, educational, or psychological processes, and/or with an opportunity to practice the same methods of observation customary to the various disciplines. Projects of this sort range from giving a child a test of some cognitive process to actually working in a community as a participant observer. Since such classes are highly unlikely to lead to general results and are not undertaken with that goal in mind, this is not considered to be research as such. Rather, they are solely a part of the practicum resources of teaching. Such course projects require the instructor to complete Form 4 of the Human Subject Approval Forms (Request for Exemption for Course Assignment), http://www.humboldt.edu/~gradst/Human_Subjects_Form_Page.html. Any potential risks which might be incurred by subjects in practicum of this sort are the responsibility of the faculty member.

The following guidelines provide recommended methodologies for implementing the ethical principles for protection of human subjects:

- Services performed strictly for the benefit of the subject do not require review unless they place the subject at risk. For example, classroom instruction is a service and does not require review; however, the use of unconventional or experimental techniques such as blindfolding or hypnosis should be submitted for review. Research surveys and questionnaires utilizing human subjects are covered by this policy and may, or may not, be exempt from IRB review.
- Submissions proposing the use of class time for research should include an explanation of the beneficence of the research to the students. Specifically, the researcher should explain how

participation in the research would be a learning experience for the students and how the research is relevant to the course of study being taught in that class. The submission should also outline the precautions that will be taken by the investigator to ensure that student participation is voluntary and free of coercion.

- Signed parental consent is routinely required for any involvement of a subject who is a minor. School officials cannot grant consent for the use of students for research without signed parental consent; signed parental consent is required in addition to any administrative approvals.
- In addition to obtaining parental consent for a minor to participate in research, the minor should also be asked for his/her assent to participate.
- A training program does not constitute human subjects research if no data are collected. However, training programs that collect individual data through questionnaires, surveys, or direct physical involvement do constitute the use of human subjects and do require consideration.
- Anonymous questionnaires and surveys do not require signed Informed Consent, but the subjects should always receive the Explanation of Study. In addition, a non-anonymous instrument may not require signed Informed Consent if the information being collected by the questionnaire or survey could in no way be damaging to the subject.
- Long-term projects, especially large grants and contracts, may require preliminary approval before all human subjects involvement has been completely defined. Such projects should be submitted for review before funding is received and the project is initiated. A preliminary submission should contain all currently available information on the proposed use of human subjects. If possible, the proposed subject pool should be described and all currently foreseen risks should be outlined.
- Standard medical or psychiatric evaluations are services; however, the use of such records for any purpose other than the patient's own treatment constitutes research and requires IRB review.
- Methods of subject recruitment should comply with all federal, state, and local laws.
- If individuals in the proposed subject pool are in a position of diminished autonomy for any reason, the submission should identify safeguards that will be implemented to ensure that individuals in the subject pool are not at risk of negative repercussions from either their agreement or refusal to participate in the research. Subject pools including persons with diminished autonomy are pools that may include students, employees, prisoners, or patients.
- Consent of a guardian is needed for any adult subject who is not autonomous or is not capable of giving fully informed consent.

For formal research, federal regulations require institutions to take formal responsibility through human subjects review. In the case of under-graduate class projects, the course instructor is considered to be responsible. It is also the instructor's responsibility to disseminate this

information to any teaching assistants or research assistants who may be under his/her direction.

Any student-initiated and/or student conducted research that does not fall under the heading of a research practicum, and which uses human subjects, requires clearance by the IRB. This includes the graduate thesis and the senior project/thesis. Student research projects are reviewed using the same principles and guidelines for the protection of human subjects in general. Since responsibility for obtaining the human subjects committee approval for student research resides equally with the student and the faculty advisor, the signatures of both are required on the review protocol.

5.2 CATEGORIES OF RESEARCH

Research involving human subjects is divided into three categories, depending on the type of research to be performed. These categories are: (a) research that is **exempt** from formal, written informed consent; (b) research that is eligible for **expedited** review; and (c) research that requires **full committee** review. All research protocols must be submitted for IRB review. Ultimately, it is the IRB that determines which category a specific proposal belongs in.

Federal law requires that research involving human subjects be reviewed once a year at a minimum.

- Approval for these projects is granted for one year only.
- Investigators of projects that last more than one year must file each year for renewal of a project, and also upon completion of a project.
- The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- The IRB shall require that information given to subjects as part of informed consent is in accordance with CFR 46.116. The IRB may require that information, in addition to that specifically mentioned in CFR.46.116., be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
- The IRB shall require documentation of informed consent or may waive documentation in accordance with CFR.46.117.
- The IRB shall notify investigators and the institution (HSU) in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it

shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

- The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

6.0 EXEMPT RESEARCH

Research activities in which the only involvement of human subjects will be in one or more of the following categories is considered to be exempt. Exempt research does not require the investigator to obtain written informed consent from human subjects.

- 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.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observations 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' responses 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) the topic of the research does not involve a very sensitive or emotional issue (e.g., personal experience with family violence, HIV, or sexual assault). Research involving educational tests, survey or interview procedures, or observation of public behavior may be considered exempt even if the provisions listed above have not all been met if the subjects are elected or appointed officials or candidates for public office, or if federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 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) the human subjects are elected or appointed public officials or candidates for public office; or (b) federal statutes(s) requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter;
- 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.

- 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; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
- 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.

7.0 EXPEDITED RESEARCH REVIEW

Human subjects research that qualifies under the classification of involving "no more than minimal risk" may be reviewed according to the procedures of expedited review set forth in the Uniform Federal Policy CFR.46.110. Application procedures for expedited review are the same as for full IRB review. Section 7.1 describes only those elements which are specific to expedited review.

Research involving no more than minimal risk can qualify for Expedited Review. An IRB member can approve expeditable proposals; full committee review is not necessary. The IRB member may need to consult with another expert member of the IRB regarding the proposed project. In some cases, the IRB will require that a research protocol be revised in order to qualify for expedited review.

7.1 MINIMAL RISK

Research involving no more than minimal risk to human subjects *means that the probability of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or*

psychological examination or tests (CFR.46.102.I). Proposals at variance with this principle will be prepared for full IRB review.

- Minimal risk is to be determined with regard to the state of vulnerability of the particular subject or subjects, especially if special populations are used as subjects.
- Research in this category may receive expedited review as specified in CFR.46.110.a-d of the Uniform Federal regulations as described in this policy. Researchers should submit proposals in the same manner as for proposals involving more than minimal risk, but should specifically state in the cover memo that the research involves "no more than minimal risk" and that expedited review is requested.

The Secretary of DHHS provides the following list of categories of research that may receive expedited review:

- Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
- Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, amniotic fluid at the time of rupture of the membrane prior to or during labor, urine to a bag.
- Collection of mucosal and skin cells by buccal scraping or swab, skin swab, or mouth washing; sputum after saline mist nebulization.
- Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, electroretino-graphy, and chest x-ray. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
- Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age

or older and who are in good health and not pregnant.

- Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- Voice recordings made for research purposes such as investigations of speech defects.
- The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given age, weight, and health of the individual.
- Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

The IRB may use the expedited review procedure to review either or both of the following: (1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk. (2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

7.2 EXPEDITED REVIEW

The protocol statement is reviewed by one or more experienced IRB reviewers designated by the Chairperson from the IRB, who have been selected to serve as a review subcommittee for the activity.

The review performed by the IRB members will verify that subjects will be placed at no more than minimal risk. The policy criterion for determining whether a subject is "at risk" is where any individual may be exposed to the possibility of injury, including physical, psychological, social or economic injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his/her needs or which increases the ordinary risks of daily

life, including the recognized risks inherent in a chosen occupation or field of service.

8.0 FULL COMMITTEE REVIEW

Projects not qualified for exempt or expedited review are considered as full review projects.

8.1 RISK-RELATED QUESTIONS

If risk is involved the answers to the following three questions will be weighed:

- Are the risks to the subject so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks?
- Are the rights and welfare of any such subjects adequately protected?
- Is legally effective informed consent obtained by adequate and appropriate methods in accordance with the provisions of the Uniform Federal Policy?

8.2 PROTECTION FROM UNDUE RISKS

The protection of human subjects from undue risks and deprivation of personal rights and dignity can best be achieved through consideration of three issues, that (1) subject participation is voluntary, indicated by free and informed consent (the subject is free to withdraw at any time without jeopardy, and may request that his/her data be destroyed), (2) the degree, nature, and management of risk to the subject and the researcher have been delineated explicitly by the researcher, and (3) appropriate balance exists between potential benefits of the research to the subject or to society and the risks assumed by the subjects. The IRB has the ultimate responsibility to determine risk with regard to human subject research, and to approve or not approve such research under the sponsorship of the University or its auxiliaries.

Federal mandate (45 CFR 46) requires that the IRB review and approve any biomedical or behavioral research involving human subjects or organs, fluids, or tissues and assure that legally effective informed consent is obtained from study subjects. Risks to subjects are minimized by (1) using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk; and (2) whenever appropriate using procedures already being performed on the subjects for diagnostic or therapeutic purposes. Appropriate safeguards to protect potentially vulnerable populations (e. g. pregnant women, fetuses, children, the mentally

disabled) are required. The Board must include persons whose primary concern is the welfare of these study subjects. The IRB examines and approves all proposed informed consent forms to ensure that subjects are provided with a clear and complete explanation of the study and its potential benefits and risks.

Investigators have many obligations, including designing the study so that the incidence of risk and stress are minimized to the greatest degree possible and that these risks are accurately described in the protocol. The investigator bears responsibility for terminating the study when hazards or risks to the subject become apparent or may be incompatible with the benefits of the study; further, investigators must report any adverse reactions associated with the study to the IRB.

9.0 APPLICATION PROCEDURES

The IRB requires the following documents for each new study involving human subjects: 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. Submit an original and one copy to the Office of Research and Graduate Studies, SH 129. Text must be double-spaced, and all pages numbered.

Researchers are entitled to timely review of research proposals. The IRB will normally complete its review of exempt and expedited research within a week and for full board review within ten working days of the submission of a complete, properly formatted proposal. In the event that the IRB is unable to complete review of proposals within 10 working days, the researchers shall be informed promptly. Upon request from researchers, the agenda of the IRB shall be reviewed to prioritize proposals by urgency for starting the research.

Exempt and expedited proposals are reviewed year round. Proposals requiring full board action cannot be reviewed during the summer.

9.1 APPLICATION AND ABSTRACT

The abstract should be 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, and risk management procedures.

9.2 THE PROTOCOL

Expedited and Full Board proposals require submission of a research protocol and consent forms.

All procedures related to the preparation of appropriate protocols as well as processes leading to their submission to the IRB are the responsibility of the University departments and researchers.

9.3 CONTENTS OF THE PROTOCOL

The **protocol** is a statement of the researcher's responsibilities toward the human subjects involved in the proposed research, and contains the information described below. It should be limited to 10 or fewer pages. A protocol is the researcher's plan of a scientific experiment or treatment. An expedited review protocol consists of a submission check list, a cover letter, an application form, an abstract, a human subjects protocol, an informed consent form, a sample survey instrument(s) or questionnaire(s), and a grant proposal, thesis or prospectus (if available), so as to provide complete information regarding activities involving human subjects. The protocol provides the IRB with the information that it needs to approve the proposed research. The principal investigator signs the protocol cover sheet, indicating that he/she will comply with the federal and university regulations outlined in the human subjects policy.

When preparing and reviewing a protocol, it is the responsibility of the investigator and the IRB to consider, among other issues, the following: the benefits and risks of the investigation, confidentiality of subject data, and the procedure for obtaining informed consent from all subjects.

Purpose and Background. The protocol must contain information pertaining to the background of a particular discipline. This section should state the relation of the proposed research to previous scientific investigations in the field including relevant laboratory and animal studies. Clear justification for the participation of human subjects at this stage of the investigation must be given. Researchers should keep in mind that most members of the IRB are not experts in the research being reviewed. Adequate lay language explanations should be provided to allow the members of the IRB to understand the objectives, the methods, and the potential results, as well as the conditions and risks to which human subjects will be exposed. The specific aims and hypotheses of the investigation should be discussed, including a definition of the area of the problem, the contribution the research is expected to make, and the relevance of the hypothesis to be tested. If specific hypotheses are not being tested, then the questions to be answered or the

information hoped to be gained should be discussed. Also, if the investigation is a pilot or exploratory one, then a discussion of the way in which the information obtained will be used in future studies should be included.

Methods Section. A detailed description of all procedures to be performed on human subjects for the purposes of research must be included. Observational or interview studies should indicate the type of contacts and interactions with their subjects and the means of observation to be used. When questionnaires are to be administered, a copy should be included. Standard psychological tests should be identified. Special attention will be given to issues of confidentiality in behavioral studies. In cases where information provided to subjects regarding procedures and purposes of the study would invalidate the objectives, the investigator should report to the IRB reasons for not informing subjects of the procedures. Devices or activities that are not customarily encountered by the subjects in their daily living or unusual applications of such devices or activities must be described in detail. Any special procedures involving unusual electrical devices, radioisotopes, or investigational new drugs (IND's) must also be described. Approval from appropriate campus or federal agencies must be obtained before IRB approval can be granted. Unusual electrical devices, chemicals, activities risking health or injury must have the Radiation Safety Officer's approval. Radioisotopes or research involving any source of radiation, and "new" drug use must be first approved by the Federal Drug Administration. A tentative time schedule for the various procedures or flow-chart where appropriate should be provided showing how long each aspect of the study will take, the frequency and timing of ancillary procedures, the nature and duration of human discomfort, and the precise location in which the study is to be conducted. Frequency, duration, and location of interviews or observations should be indicated in behavioral or social science studies.

Subjects. Effects of sample size on the magnitude of risk and problems of risk management will be considered by the IRB. Justification must be provided for the use of subject groups that are members of a population whose capability of providing informed consent is or may be absent or limited. These include children, persons with diminished mental capacity, the senile who are confined to institutions (whether by voluntary or involuntary commitment), the unborn child or fetus, and pregnant women. A pregnant woman's ability to provide consent is limited insofar as she can participate only in activities whose purpose is to (1) meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

A detailed and specific discussion of potential problems involving the subject groups must be given.

Potential Benefits. This section must present a justification for the proposed study. The discussion should focus on the significance of the new knowledge that is being sought and an evaluation of the benefits to the subjects and/or society with respect to the risks involved in the study.

Potential Risks. A discussion of the risks, if any, to the subject is required. Such deleterious effects may be physical, psychological or social. Some research involves neither risks nor discomfort, but rather violations of normal expectations. Such violations, if any, should be specified.

Management of Risk. A discussion of the management of risk is required. Procedures for protecting against or minimizing potential risks should be described (including confidentiality safeguards). An assessment of their likely effectiveness should be discussed also. Management of risk procedures ranges from those applicable to a group (such as the exclusion of pregnant or potentially pregnant women from a study involving a new drug) to those applicable to an individual subject.

Procedures for Risk Management.

- Obtain informed consent.

- Maintain anonymity or a high degree of confidentiality through secured data and research records.

- Debrief human subjects after their participation in the experiment is concluded. Information should be appropriate for the individual (i.e., based on experimental situation and performance). Subjects should be supplied with a summary of the project when it is completed.

- All possible alternative methods should be explored prior to the selection of a procedure which would place a human subject at risk. Procedures selected should result from an attempt to minimize stress while maximizing the usefulness of the information obtained.

- Researchers should concern themselves with how the information obtained from the study will affect individual human subjects as well as the community in general.

- Adequate access to first aid must be available in any study involving even minimal physical risks.

- Ready access to medical personnel, services and emergency care must be provided in any study involving significant potential physical risk.

- Adequate access by referral to psychological treatment must be available in any study involving psychological risk.

Subject Compensation. If subjects are to be compensated, the nature of the compensation and its influence on subject participation must be discussed. Experimental subjects may be reasonably reimbursed for their participation in an experiment. Compensation to subjects should never be such as to constitute an undue inducement or coercion.

Personnel. Identify all personnel who will participate in or assist in the conduct of this research. Identify each individual by name, title, and responsibility in this research project. Briefly outline each individual's qualifications. For procedures requiring special skills on the part of the investigators, licensure, accreditation, and/or background of the investigators qualifying them for the performance of these procedures should be indicated.

Other. The IRB relies on the expertise of the researchers to provide insight about any peripheral benefits or potentially harmful effects of the conduct of the research. Based on past experience and knowledge, investigators should identify any extraordinary moral, legal, or ethical concerns, either beneficial or harmful, which may have been linked to this type of research.

When the proposed project is submitted to Research and Graduate Studies, a preliminary review of the protocol is done to determine whether (a) the project is exempt under the regulations or is to be reviewed under the expedited or full review process (b) the protocol meets the general requirements for review under the regulations; and © the informed consent form contains the required elements and is in satisfactory form for review.

Anonymity exists when there are no identifiers whatsoever on project materials which could link the data with individual subjects. Even the investigator cannot know the identity of participants.

Confidentiality is the right of privacy and of non-release of disclosed personal information. The investigator should protect subjects against invasion of privacy and loss of confidentiality. Lack of secure handling of completed personality tests, questionnaires, interview protocols or data, and recorded materials, creates risk and must be avoided.

9.4 THE CONSENT FORM

Any project proposing to place any individual at risk is obligated to obtain and document legally effective informed consent. Informed consent means the knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without

undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. (See sample consent form included in IRB form package.)

If the subjects are minors or are not capable of giving consent, parental, guardian or other legal representative consent is required. Use of a written consent form that includes all the basic elements of informed consent must be documented by a signature of the subject or legally authorized representative. When subjects are minors, their assent to participate is also required.

A consent form documents informed consent and is designed to protect the investigator and the institution against legal liability.

The consent form should be a statement addressed to the subject and should read as such. It must be in language the subject can understand. Avoid or define technical terminology, adjust for educational background and ages, and provide translations in other languages when subjects do not understand English.

10.0 INFORMED CONSENT

Research investigators are responsible for obtaining informed consent and for insuring that no human subjects will be involved in the research prior to obtaining their consent. In obtaining informed consent, investigators must avoid the possibility of coercion or undue influence. Unless otherwise authorized by the IRB, investigators are responsible for insuring that legally effective informed consent shall:

- Be obtained from the subject or the subject's legally authorized representative;
- Be in language understandable to the subject or the representative;
- Be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
- Not include exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, *the institution or its agents from liability for negligence.*
- Researchers must view informed consent as something that must be maintained throughout the research process.

10.1 REQUIRED ELEMENTS FOR INFORMED CONSENT FORMS

The written consent form must include the following items. In addition, special provisions are required when subjects are from special populations.

- A statement that the study involves research;
- An explanation of the purposes of the research;
- A description of the procedures to be followed;
- The expected duration of the subject's participation;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A statement describing how confidentiality of records identifying the subject will be maintained;
- An explanation of whom to contact for answers to questions about the research (researcher's name and phone/email address, and that of the faculty advisor if investigator is a student, or the Dean for Research and Graduate Studies if investigator is faculty or staff); regarding research subjects rights; and in the event of a research related injury to the subject;
- Statement that: participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. Subjects will be given a copy of the consent form.

10.2 ADDITIONAL ELEMENTS (AS APPROPRIATE)

- For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained, and who is responsible for payment of medical expenses;
- For research projects that involve videotaping, a videotape release form must be attached to the written consent form (if the investigator anticipates use of the tapes beyond the scope of the initial research project, the written consent form must indicate (a) who will view the tapes, (b) for what purpose, and (c) when the tapes will be destroyed);
- If subjects will be paid, all information concerning payment, including amount and schedule of payment;
- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) which are currently unforeseeable;
- Identification of any procedures which are experimental;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

10.3 DOCUMENTATION OF INFORMED CONSENT

The consent form is a written document that contains the required elements of informed consent, to be read by the subject or the subject's representative or by the investigator to the subject. Investigators shall be responsible for insuring that informed consent is documented by the use of a written consent form and signed by the subject or, the subject's legally authorized representative, unless this requirement is specifically waived by the IRB. Each person signing the written consent form must be given a copy of that form.

10.4 WAIVER OF DOCUMENTATION OF INFORMED CONSENT

Under certain conditions, the IRB can waive the requirement that the subject sign the consent form. However, waiver of documentation of informed consent does not constitute waiver of informed consent. The IRB may waive the requirement to obtain a signed consent form for some or all of the subjects if one of the following conditions exists:

- The consent document is the only record linking the subject and the research and the principle risk would be potential harm resulting from a breach of confidentiality. (Subjects will be asked whether or not they want documentation linking them to the research, and their wishes will prevail);
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- The research of minimal risk involving the use of questionnaires, and the required elements of informed consent are included in an introductory letter attached to the instrument, which includes a statement that completion and return of the questionnaire will constitute consent to participate.

10.5 VERBAL CONSENT

Only in special and/or unusual circumstances can the consent of the subjects be obtained orally. Waiver of prior written informed consent must be approved by the IRB. A waiver of prior written informed consent might be granted in the case where: (a) the risk to the subject is minimal; (b) use of primary procedures for obtaining consent would invalidate important

research objectives; or alternative means would be less advantageous to the subjects. Oral presentation of the elements of informed consent should be used only when it is the most appropriate means of conveying relevant information to the subject, thus adapting the presentation to the subject's capacities.

The presentation maybe made in either of two ways. A written consent document that sets forth the required basic components of informed consent may be read to the subject or the subject's representative and the investigator will allow the subject or representative ample time to read and consider the document before it is signed. Or the IRB may approve a short written form describing the particulars of required informed consent that are to be presented orally to the subject or representative. Where oral consent is allowable, investigators shall insure that: a witness is present at the oral presentation; the short form is signed by the subject or the representative; the witness signs both the short form and a copy of the written summary of the oral presentation; the person obtaining consent signs a copy of the summary; a copy of both the short form and summary is given to the subject or the representative; and the written summary of what is to be said to the subject or the representative receives the prior approval of the IRB.

10.6 WAIVER OR ALTERATION OF INFORMED CONSENT

The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided one of the following sets of conditions exists and is documented:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine (a) programs under the Social Security Act or other 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; or (d) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration.
- The research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

11.0 REVIEW OUTCOMES

After review and discussion of the protocol and application, the IRB may take one of the following four actions: (1) approval, (2) approval after modification, (3) disapproval, and (4) the suspension/termination of a previously approved protocol. Actions (3) and (4) may only be taken at convened meetings at which a majority of the members are present.

11.1 APPROVAL OF RESEARCH

In any review, the reviewers will determine that:

- Participation of human subjects in the project is justified.
- Risks to subjects are minimized by using appropriate procedures.
- Risks are justified in view of anticipated benefits to the subjects and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable. Justification is required if the subject population is restricted to one gender or ethnic group. (In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, persons with disabilities, or economically or educationally disadvantaged persons.) Adequate provision is made for confidentiality of data and anonymity of participants in any published record.
- Adequate provision is made for the rights and welfare of participants who are mentally, physically, economically or educationally disadvantaged.
- Adequate provision is made for obtaining informed consent of the subjects, including those for whom English is not their first language.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by CFR.46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

11.2 REQUIRES MODIFICATIONS

This action involves major or minor modifications to some part of the proposed study. The modifications or conditions set by the IRB include such items as revising the consent form to explain the procedures more clearly, adding a Spanish version of a consent form, restrictions on the use of certain procedures or subject groups as necessary for the protection of human subjects. The IRB may require significant modifications in the research protocol. This occurs when the IRB feels that it has insufficient information to take action, or when it feels that the research design contains significant risks and should be revised to minimize those risks to human subjects. The IRB may request the investigator to discuss problems with the IRB directly or through a selected member. Modified research protocols must be resubmitted for approval. The IRB may choose to use expedited review for resubmissions involving minor modifications.

11.3 DISAPPROVAL

In this case the IRB makes the decision that the potential benefits of the research do not outweigh the risks to the subject.

11.4 SUSPENSION OR TERMINATION

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head (CFR.46.113).

12.0 DISPOSITION OF DECISIONS

Approvals, recommendations, restrictions, conditions, or disapprovals are communicated to the researcher through the office of the appropriate administrator, as appointed by the President. At the time of transmittal of approval, the IRB will also inform the researcher of the expiration date of the approval.

If an application is not approved as conforming with the Uniform Federal Policy for the Protection of Human Subjects and the University, the IRB shall forward to the researcher a

statement setting forth in detail the reasons for the non-conformity and the recommendations of the IRB for modification of the research proposal. (CFR.46.109(d)).

12.1 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 appropriate administrator (Dean, Research and Graduate Studies) 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.

12.2 ARBITRATION

Any matters requiring arbitration between the IRB and a researcher 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 researcher, will seek resolution of the differences. They will report their findings to the Board and the researcher, 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.

13.0 DOCUMENTATION

Researchers. Investigators are required to make and keep written records of the IRB reviews and decisions on the use of human subjects and to obtain and keep documentary evidence of informed consent of the subjects or their legally authorized representative. Such forms must be retained on file by the responsible individual for a minimum of five years after termination of the project.

In compliance with Uniform Federal Policy on the Protection of Human Subjects, researchers will maintain records of research data for at least three years after the research is concluded.

The researchers must periodically review research results to assure (1) that harm has not occurred and (2) that the ongoing research protocol is producing adequate results such that benefits of the research continue to balance risks to human subjects. If unanticipated harm occurs or results are inadequate to assure a balance of risks and benefit, the researcher must report immediately to the IRB.

The IRB. The IRB is required to keep copies of all documents presented or required for initial and continuing review by the Board. The records of the IRB pertaining to individual research activities are not accessible to persons outside the Board and the individual researcher, except for purposes of audit or inspection by federal agencies and appropriate University administrators to assure compliance with the Uniform Federal Policy.

The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, reports submitted by investigators, and reports of injuries to subjects.
- Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in or

disapproving research; and a written summary of the discussion of controversial issues and their resolution.

- Records of continuing review activities.
- Copies of all correspondence between the IRB and the investigators.
- A list of IRB members in the same detail as described in CFR 46.103.(b)(3).
- Written procedures for the IRB in the same detail as described in CFR.46.103.(b)(4) and CFR 46.103.(b)(5).
- Statements of significant new findings provided to subjects, as required by CFR 46.116.(b)(5). The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

The Institution. It is the responsibility of HSU through the appropriate administrator or administrative office, as appointed by the President, to assure compliance with and provide documentation of compliance with the Uniform Federal Policy for the Protection of Human Subjects.

Research that is covered by the Uniform Federal Policy and that is conducted or supported by a federal department or agency must provide written assurance satisfactory to the federal department or agency head that it will comply with the requirements set forth in the policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, DHHS, and approved for federal wide use by that office. When the existence of an DHHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Protection from Research Risks, DHHS.

Federal departments and agencies will conduct or support research covered by this policy only if HSU has an approved assurance and only if HSU has certified to the federal department or agency head that the research has been reviewed and approved by the IRB provided for in the

assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

- A statement of principles governing HSU in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by HSU, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by HSU itself. This requirement need not be applicable to any research exempted or waived under CFR 46.101. (b) or (I).
- Designation of one or more IRBs established in accordance with the requirements of the Uniform Federal Policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and record keeping duties.
- A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB membership shall be reported to the department or agency head, unless in accord with CFR.46.103 (b) (3) of this policy the existence of an DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, DHHS.
- Written procedures which the IRB will follow for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.
- Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval.

The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of HSU the obligations imposed by the Uniform Federal Policy and shall be filed in such form and manner as the federal department or agency head prescribes.

Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under CFR 46.101.(b) or (I). HSU shall certify that each application or proposal for research covered by the assurance and by CFR 46.103. of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the federal department or agency to which the application or proposal is submitted. Under no condition shall research covered by CFR 46.103. of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. If HSU is without an approved assurance covering the research, HSU shall certify within 30 days after receipt of a request for such a certification from the federal department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to HSU.

14.0 DURATION OF APPROVAL AND RENEWAL APPLICATIONS

Federal policy requires that the IRB conduct at least an annual review of approved research activities, (CFR 46.109.(e)). Researchers should indicate the expected overall duration of the research when submitting an initial protocol. Renewal applications should be made before the date of expiration of IRB approval, bearing in mind the time needed for review and that research activity must cease at expiration date if renewal has not been obtained.

The IRB will determine the term of approval and will notify the researcher of the date of expiration of approval at the date of approval. Notice of expiration of approval will also be sent to the principal investigator by the chair of the IRB approximately six weeks before the expiration date of any currently approved protocol. Approval of a protocol is granted to the principal investigator. If the principal investigator ceases to be responsible for the study, approval automatically ceases. Should a new principal investigator desire to continue the study, reapplication (as for a renewal see below) to the IRB is required

15.0 RENEWAL APPLICATIONS AND MODIFICATIONS OF PROTOCOLS

Renewal of approved protocols is required annually and is also required if the principal investigator changes. If during the course of any research, training, or demonstration, a change in plans is made so that human subjects are now to be used, or that the research methods or techniques are significantly different, or new hazards are evident, a statement of such change in plans must be submitted to the IRB, and an approval of modification of the existing protocol must be obtained. In general, any change which alters the risk/benefit balance or which modifies the informed consent in some way, requires approval.

Renewal applications require a copy of the current or new consent form and (1) a **summary** of the previous (approved) protocol, or copy of the previous protocol; (2) a **status report**. This should be a brief discussion of the work accomplished to date, including particularly:

- The number of subjects studied and the number approached who refused permission;
- A discussion of the experience of the subjects undergoing study, with particular reference to any adverse events occurring to them during the conduct of the study (if no adverse event has occurred, it should be stated, rather than omitting this item altogether); and
- A brief description of the scientific or research results, if any, to date.

Progress reports should not be photocopies of papers either published or submitted for publication. The papers primarily inform their readership of scientific advances. It is necessary to inform the IRB, in as concise a manner as possible, of the results only as they influence the balance of benefit to risk to human subject. Published papers may be appended as evidence of benefits of the research.

Modification applications require a copy of the current or new consent form and: (1) a **summary** of the previously approved protocol, or copy of the previous protocol itself and (2) a **description** of any modifications to the current or previous protocol which are desired. For these, the description and justification should proceed much as outlined for a new application; that is the background or reason for modification, benefits, and risks, etc. When responsible positions are assumed by new personnel in the execution of the protocol (such as change of the principal investigator) a description of the background of the individuals with regard to the work described in the protocol (as in the original application) should be given.

16.0 UNANTICIPATED PROBLEMS

Any unanticipated problems involving risk to subjects or others, including adverse reactions to biologicals, drugs, radioisotope labeled drugs, or to medical devices must be reported immediately to the IRB and to any federal agency sponsoring the project by the researcher.

Reports should include:

- Identification of individual(s) involved;
- Identification of principal investigator, title of project and project number;

- A description of adverse reactions and any possible association with the experimental procedures, drugs, and medical devices.
- Any relevant information on the subjects (previous exposure to drugs, therapy, case history, and background information).

17.0 VIOLATIONS OF POLICIES AND PROCEDURES

Noncompliance with these policies and procedures is subject to University disciplinary action. Violations of these policies and procedures should be reported to the IRB immediately.

The IRB will review allegations of violations of these policies and procedures, and will follow the policies and procedures as set forth in the Humboldt State University Policy for Protection against Misconduct in Science, and other regulations governing faculty, staff, and student ethical conduct as appropriate.

If any research which is federally funded is found to be in violation of any of the federally mandated portions of this policy, or of appropriate federal regulations regarding the protection of human subjects, the IRB shall report to the appropriate agency on behalf of the researcher, if the researcher fails to report.

In any instance where IRB requirements are not being followed, the IRB shall inform the principal investigator and also the appropriate administrator, as appointed by the President, who will be asked to enforce the requirements. In the event that the principal investigator does not comply, the appropriate administrator will terminate the research. Such action will be accompanied by a letter to the principal investigator, stating the reason for the action.

18.0 ADVICE AND CONSULTATION

Researchers and departments may call upon the IRB for informational consultation. The IRB will maintain a rotating panel of consultants for this purpose. This panel will consist of current and previous members of the IRB, in addition to other individuals approved by the IRB.

Any consultation extended is informational in nature. It is neither interpretative nor decisional, as these are solely the prerogatives of the IRB in its review function.

19.0 OMISSIONS

In the event that issues related to the use of human subjects in research at HSU are not covered by this policy, the IRB will rely on the Uniform Federal Policy.

20.0 AMENDMENTS

Minor amendments to this policy require the approval of two-thirds of the membership of the IRB. Major revisions of this policy require the approval of two-thirds of the membership of the IRB, the endorsement of the Provost and the Vice President for Academic Affairs, and the approval of the President.

New campus or California State University requirements, or changes in state or federal laws shall be incorporated in this document by the appropriate administrator without further review.

The final authority for amendment of these policies and procedures, and for the adoption of a new revision rests with the President.

For current information on the Policy for Protection of Human Subjects, refer to the federal web site: <http://www.hhs.gov/ohrp/>

The regulations referred to in this document are available at the United States Department of Health and Human Services (regulations), <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.