SAN JOSE STATE UNIVERSITY
ONE WASHINGTON SQUARE
SAN JOSE, CA 95192

S08-7, Policy Recommendation, Policy for Protection of Human Research Subjects

Legislative History:

At its meeting of May 12, 2008, the Academic Senate approved the following Policy Recommendation presented by Senator Kaufman for the Curriculum and Research Committee.

Rescinds F90-4

Action by University President: Approved by President Don Kassing on May 15, 2008.

Policy Recommendation

Policy for Protection of Human Research Subjects

Whereas: The Academic Senate in SM-F05-1 created a Human Subjects – Institutional Review Board Task Force to review and suggest modifications to the current policy and practice in reviewing use of human subjects for research at SJSU; and

Whereas: These policy suggestions emerge from the following SJSU policies: F90-4: "POLICY FOR PROTECTION OF HUMAN RESEARCH SUBJECTS; ETHICS; INSTITUTIONAL REVIEW BOARD (IRB)'; S99-11: "Conflict of Interest Policy for Principal Investigators"; F00-1: Policy Recommendation; "Modification to F90-4, Policy For Protection of Human Research Subject: Ethics: Institutional Review Board"; S05-3: POLICY RECOMMENDATION "INSTITUTIONAL REVIEW BOARD-HUMAN SUBJECTS TRAINING FOR INVESTIGATORS;" and

Whereas: The Task Force has crafted a suggested policy that was submitted to the Curriculum and Research Committee for further action, drawing upon in addition to its own language, extensive regulatory language which comes directly from the United States Department of Health and Human Services Code of Federal Regulations Title 45 (Public Welfare), Part 46 Protection of Human Subjects (such usage is indicated by the use of the CFR citation in parentheses), additionally, language and policy were drawn, with permission, from the Guidelines for Protocol Development and Evaluation from San Diego State University's Human Research Protection Program: Guidance, Standards and Practices (This document was designed for use across CSU campuses and was developed by Camille Nebeker and Gayle Simon, Division of Research Affairs, San Diego State University.); and

Whereas: The suggested policy submitted by the Task Force has been considered and modified by the Curriculum and Research Committee (as indicated by strikethroughs and underscores); therefore be it

Resolved:	That the attached policy be implemented.
Approved:	April 28, 2008
Present:	Bridgeman, Buzanski, Cooper, Cushing, Kaufman, Nance, Roldan, Schultz-Krohn, Stacks, Van Hooff
Absent:	Maldonado-Colon, Romo, Yu
Vote:	10-0-0
Financial Impact:	Neutral relative to current policies and procedures

TABLE OF CONTENTS

5. IRB shall assess the need for a written consent form
6. Informed Consent Guidance
7. Components of a Consent Form
8. Structure of a Consent Form
9. Obtaining Parental Permission
10. Obtaining Assent/Dissent from Minors
11. Short Form Written Consent
12. Consent Translation

G. Alternative Consent Procedures
1. Public agency or service research
2. Impact on research
3. Conditions for IRB consideration
4. Waiver of written consent
5. Obtaining Consent in Exempt Research

POLICY FOR PROTECTION OF HUMAN RESEARCH SUBJECTS

I. Intention

A. SJSU shall comply with all appropriate statutes governing human research. In addition, non-federally funded or unfunded research shall undergo the same review as if it were federally funded.

II. Responsibilities

A. San Jose State University acknowledges and accepts responsibility for protecting the rights and welfare of human subjects in research.

1. The Principal Investigator is responsible for conduct consistent with the ethical treatment of their participants and data. A principal investigator is the individual in charge of a research project and must be qualified in the area of the proposed human subjects research. The principal investigator must assume the responsibility for compliance with the present policy. A student may not serve as a Principal Investigator, but may be sponsored by a faculty member to be an investigator.

Principal Investigator responsibility includes:

a. Carefully anticipating interaction with human subjects in the proposed research

b. Registering/submitting a project proposal to the IRB for review

c. Adhering to all proposed actions

d. Informing the IRB of any changes in the proposed research

e. Informing the IRB of any Significant Adverse Events (SAE) within five days of an event.

f. Carefully monitoring research by students, staff or associates, conducted under the guidance of the Principal Investigator.

2. The SJSU Institutional Review Board is responsible for the appropriate review and oversight of research activities. It also reports any SAE to the Institutional Officer.

3. SJSU's Institutional Officer, the Associate Vice President for Graduate Studies and Research (AVP/GS&R, has administrative authority for the protection of human subjects. The Associate Dean for Graduate Studies and Research will act as an ex-officio member of the IRB, will maintain IRB files, coordinate meetings, and process protocol reviews. The IRB at SJSU is a 13 to 15-member operating committee that is appointed by the Academic Senate and reports to the Curriculum and Research policy committee. IRB members from SJSU receive three-year appointments; community members and students serve for one year. The names and affiliations of IRB members are reported annually to the Office for Human Research Protections, Department of Health and Human Services.

III. Scope of the Policy

A. The constraints on Federally Funded Research embedded within TITLE 45, PUBLIC WELFARE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, PART 46: PROTECTION OF HUMAN SUBJECTS of the code of federal regulation (hereinafter 45 CFR 46) and other applicable statutes shall be applied to human subjects research performed at SJSU.

B. The definition of research is from 45 CFR 46.102(d). Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable 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 described in the 1979 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research Belmont Report: Ethical Principles And Guidelines For The Protection Of Human Subjects Of Research, "...the term 'research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships)". The IRB considers generalizable knowledge to include the dissemination of research findings beyond the boundaries of the institution (e.g., publication (including thesis or dissertation) or presentation or use outside the specific instructional setting. The exception to the parameters defined occurs:

1. When a report of findings is issued to an agency that has contracted with the university to acquire programmatic information (e.g., needs assessment, program evaluation, quality control). Studies conducted for the purpose of program evaluation, needs assessment, or quality control in which findings are solely intended for use in internal program planning and development and are not designed to contribute to generalizable knowledge (publication or presentation) are not subject to IRB review but should be registered with the IRB.

2. Projects are not subject to IRB review when an employee of the institution consults on research but does not receive or possess identifiable and private information about persons participating in the study. In addition, projects are not subject to IRB review when an employee of the institution is engaged in research as a consultant through a non-institutional contract. In this case, research activities must occur outside of his/her institutional employment and he/she may not reference the institution in documents or publications associated with any reported outcomes.

C. Research is considered to involve *human subjects* if it involves living individuals about whom an investigator obtains data through intervention or interaction with the individual(s) or obtains identifiable private information (45 CFR 46.102(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.

There is human subjects involvement when:

1. Human beings are asked to participate physically in an activity or to donate their tissue, organs, fluids and other bodily material;

2. Information is sought from human beings directly (as through interview or questionnaire) or indirectly as through observation and individual responses are identifiable;

3. Information concerning specific, individually identifiable human beings is asked for from third parties- whether through access to files, data banks or other means – or through direct inquiry of third parties concerning the individuals in question.

4. Although an activity may be considered research (…systematic investigation designed to contribute to generalizable knowledge…), it may not involve human subjects (…a living individual about whom information is obtained through intervention or interaction). Except for the populations defined above, persons involved in a research activity are not considered to be human subjects when the following apply:

> a. The information collected is not about the individual. That is, the person interviewed/surveyed is asked to provide information specific to his/her expertise or profession as opposed to personal information about him/herself (opinions, thoughts, or perceptions). For example, a welder asked

to describe the composite of shielding gas, shielding gas flow rate, and formation of the weld bead is not disclosing information about him/herself and, as such, is not a research subject. Likewise, an entomologist who describes the varieties of pesticide used to control a specific pest and to identify the types of pesticides that are used most frequently is contributing his/her expertise rather than information about him/herself.

b. The information must be about a living individual to qualify as a human subject. Review of death records does not involve human subjects. However, analyses of biologic specimen (blood, tissues) or nonpublic records do require IRB review and approval before analysis may begin.

c. When an activity uses diagnostic or classification data for epidemiologic and analytic purposes that are not identifiable by individual or group and when such data are not proposed for a use that conflicts with the conditions under which the data were originally obtained;

d. When research data are taken from the public domain and may include data traceable to known individuals or social groups who have clearly made both the information and their identities available for any forms of scrutiny and analysis within the limitations set by statutes concerning libel;

e. When observed behavior takes place in a public arena or locale and is observed as aggregate behavior in such a way as to preclude any post-facto identification of individuals.

IV. Principles and Applicability

A. SJSU human research activities are to be constrained by the requirements of the code of federal regulations TITLE 45, PUBLIC WELFARE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, PART 46: PROTECTION OF HUMAN SUBJECTS as if all SJSU research were federally supported.

1. Where state or federal law requires more stringent principles, those will be applied.

2. Where professional representative organizations such as the American Medical Association, the American Nursing Association, or the American Psychological Association, have established more stringent principles, individual Principal Investigators are encouraged to consider those principles when designing or submitting research.

3. Where research takes place in foreign countries, comparable foreign statutes which provide additional protections for human subjects will also apply.

4. Where a research project has been approved by the IRB of a separate agency with a Federal Assurance of Conformance, that research project need not be submitted for IRB approval at San Jose State University. A copy of such IRB approval should be submitted to the SJSU IRB coordinator for university records.

B. Policies and procedures presented here are applicable to all research that, in whole or in part, involves human subjects if the research is sponsored by SJSU, or the research is conducted by or under the direction of SJSU employees, auxiliary employees, and/or students (including student/faculty collaborative research) under the auspices of SJSU or uses SJSU time, facilities, resources and/or students (in their role as SJSU students). Student research must be sponsored by a member of the faculty.

C. Policies and procedures presented here are explicitly not applicable to courses that deal with established research methodology and which have been identified by the IRB as research practica. Numerous departments offer courses that require students to undertake small projects in which people are interviewed, observed, or otherwise serve as human subjects. The primary purpose of providing training in research methods is for the student to become more knowledgeable about the research process. Instructors may assign a project, in conjunction with the course, in which students design a study, recruit participants, collect and analyze data and report their findings in the form of a final paper. Since the intent of the project/assignment is to train students, the assignment is not considered to be research as defined within the federal regulations and is not subject to IRB review. The course instructor is responsible for including information about ethical research practices and providing direct supervision

of each project. Projects conducted for this purpose should not exceed minimal risk, or target special populations or include sensitive subject matter. The instructor of such a course is required to assure that procedures associated with, and data collected from, human subjects within these settings conforms to the principles and guidelines for protection of human subjects established by 45 CFR 46 and related rules. Research exempt from formal review, but whose conduct also requires respect for individual rights and welfare should conform to ethical norms and use informed consent. Instructors are expected to be particularly vigilant regarding protection of human subjects when research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

If the course assignment produces results that may be of interest to the scientific community, the IRB recommends that the student replicate the study under an IRB-approved protocol. The IRB does not have the authority to approve research retrospectively. If the primary intention of the student and faculty supervisor is to publish the data collected from the student's class project, then IRB approval is needed prior to commencement of recruitment and data collection.

D. Policies and procedures presented here are applicable to any student-initiated and/or student-conducted research that uses human subjects that do not fall under the heading of a research practicum.

1. Explicitly included are: undergraduate independent study, undergraduate and graduate courses in which the student is the initiator of the human subjects research, and graduate projects and/or theses.

V. Institutional Policies

A. At SJSU, the Human Subjects Institutional Review Board (IRB) shall review and have authority to approve, require modifications in, or disapprove all research involving human subjects conducted at SJSU or in the name of SJSU.

1. The IRB shall have the authority to suspend or terminate approval of research involving human subjects that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to human subjects.

2. Research that has received IRB approval may be subject to further review by officials of the University; however, no official may approve and authorize research that has not been approved by the IRB.

3. Termination of research approval

> a. Either the IRB or the Institutional Officer may cause approval for research to be terminated, if, in the judgment of the IRB or institutional officer, there has been a material failure to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

4. The IRB shall have access to all information and records necessary to conduct an adequate review of all proposed and ongoing research involving human subjects to safeguard their rights and welfare.

5. The IRB shall require that information that it deems necessary to protect the rights and welfare of human subjects be given to the subjects as part of obtaining informed consent from the subjects.

6. The IRB shall require documentation of informed consent if human subjects will be exposed to more than minimal risk. For minimal risk, investigators should ensure that participants know that their participation is voluntary and that the participant can stop at any time.

7. The IRB shall conduct continuing review of research procedures involving human subjects at intervals appropriate to the degree of risk.

8. In all cases, IRB approval for research shall not extend beyond a year. The PI may request an up-to-one-year extension annually.

9. SJSU shall provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization of human ova; prisoners involved in research; and children involved in research. SJSU will also consider the need for additional safeguards for research involving individuals institutionalized as mentally disabled and other potentially vulnerable groups.

Research otherwise exempted from mandated federal review and listed in Section VI.C.1. will require review by the IRB if it involves these vulnerable populations as human subjects.

10. When research covered by this policy is covered by or in cooperation with another entity, all provisions of this policy remain in effect for that research. To avoid duplication of effort, a copy of an IRB approval obtained in another institution established under assurance of compliance with federal guidelines should be submitted to the SJSU IRB coordinator for university records.

11. SJSU shall make available to each individual conducting research involving human subjects a copy of this policy on request.

VI. Description of Procedures

A. Institutional Review Board (IRB)

1. SJSU has delegated administrative authority for the protection of human subjects to the Associate Vice President for Graduate Studies and Research (AVP/GS&R). The Associate Dean for Graduate Studies and Research will act as an ex-officio member of the IRB, will maintain IRB files, coordinate meetings, and process protocol reviews. The IRB at SJSU is a 13 to 15 - member operating committee that is appointed by the Academic Senate and reports to the Curriculum and Research policy committee. IRB members from SJSU receive three-year appointments; community members serve for one year. The names and affiliations of IRB members are reported annually to the Office for Human Research Protections, Department of Health and Human Services.

2. The IRB shall be comprised of persons from diverse backgrounds to promote complete and adequate review of research proposals involving human subjects, shall include both male and female members, at least one member whose primary expertise is in a nonscientific area, and at least one member who is not affiliated in any way with SJSU. The IRB shall include one physician and an additional physician or licensed health professional.

3. When research involving a category of vulnerable subjects (e.g., prisoners, children, institutionalized mentally disabled) is to be reviewed, the IRB shall consider the inclusion in its reviewing body one or more individuals who have as a primary concern the welfare of these subjects.

4. SJSU Membership

a. Associate Dean for Graduate Studies and Research (ex officio, nonvoting)

b. IRB coordinator (ex officio, non-voting)

c. Membership shall provide for one faculty member from each Senate representative unit with an additional faculty member from each of the Colleges of Education, Social Sciences, and Applied Sciences and Arts

d. Department of Education (ED) regulations require, in addition, that when an IRB reviews research for one of its programs that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB must include at least one person primarily concerned with the welfare of these subjects [34 CFR 350.3(d)2); 34 CFR 356.3(c)(2)].

5. IRB Subcommittees

a. In order to improve IRB member training and increase transparency among the SJSU research community, three subcommittees will be available to consult and review proposals. The subcommittees are broadly defined by topic area to manage most expedited applications:

(1) Clinical health-related fields involving physical interventions, which take biological samples, or are expected to have physiological effects, including kinesiology

(2) Education

(3) Topics in social scientific research, without physical intervention

b. The Chair of the IRB would assign members to subcommittees. A subcommittee of the IRB is defined as one or more experienced IRB members designated by the IRB Chair or IRB Administrator to act on behalf of the committee when action by the full board is not required (45 CFR 46.110). A subcommittee is designated to review studies or reports eligible for expedited or exempt review, that is, studies that involve no more than minimal risk and comply with either the exempt (45 CFR 46.101) or expedited categories (45 CFR 46.110). Members will be identified by subcommittee on the IRB website so that members of the research community may discuss projects with the appropriate members in advance. The IRB coordinator is also available to the university community for consultation.

B. Protocol Review Procedures

1. Required training. Prior to submission of a research protocol to the IRB any SJSU employee planning to perform or sponsor student research involving human subjects must complete and file with the GS&R office, an affirmation attesting to the successful completion of all training courses required of IRB members. The nature of that training and access to it will be provided on the IRB website.

2. Prior to data collection two copies of the research protocol shall be submitted to the IRB for review. Student research must be sponsored by a member of the faculty. All required forms or verified internet links must be available from the office of the AVP/GS&R.

3. The protocol shall provide a complete description of the procedures used to obtain data from human subjects in the proposed research. In the protocol, research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research subjects, delineate the researcher's responsibilities toward the human subjects involved in the research, and ensure that pertinent regulations are observed.

4. Protocols shall be assigned to individual IRB members on a rotating basis to assess risk.

C. Administrative Review Categories

Research that is considered minimal risk and that meets federal criteria for an exempt or expedited review (e.g., use of existing data; some survey or interview procedures) may be eligible for review through administrative procedures (45 CFR 46.101 & 45 CFR 46.110). The research protocol is evaluated to determine whether criteria are met to justify an exempt or expedited review. Graduate Studies and Research, in consultation with the IRB, will review and verify new protocols that are identified as exempt. Notification of concurrence with the exempt status, including citation of the specific exemption category, will be conveyed in writing or electronically to the investigator. All nonexempt research will be reviewed through IRB subcommittee (expedited) or by convened committee. Research that involves data collection from adults using a survey or interview format are exempt unless the questions deal with a sensitive aspect of a subject's behavior such as illegal conduct, drug use, sexual behavior, or the use of alcohol. Research involving protected categories such as pregnant women and/or fetuses, prisoners, or the institutionalized mentally disabled cannot be exempt. Studies receiving an exempt or expedited review are reviewed on a first come first serve basis. Review notification will be sent electronically and on University letterhead to investigators in a timely fashion following application submission for an administrative review.

1. Exempt Review

a. The majority of studies that involve data collection from adults using a survey or interview format are exempt unless the questions deal with a sensitive aspect of a subject's behavior such as illegal conduct, drug use, sexual behavior, or the use of alcohol.

b. Surveys and interviews of children are not exempt; however, children can be included if the research meets the criteria of category one described in 45 CFR 46.101. The Federal guidelines state that “research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods” may be exempt. However, if the work is to be published, such as in a student thesis, it may not be exempt.

c. If the subject's identity is not recorded (anonymous) and/or the interview/survey questions are considered non-sensitive, then the research will probably be exempt. If the subject's response to the questions would pose a risk to that person if disclosed, then the research would receive an expedited review rather than an exempt review.

d. For all research, the investigator is required to provide adequate information about the research to potential subjects so that an informed decision can be made regarding participation. In research that meets the criteria for exemption, the investigator can deliver this information verbally or both verbally and in writing based on an IRB approved script or consent statement.

e. Exemption is not the same as exclusion from IRB purview. Exempt research must still be submitted to the IRB for registration.

f. Human subjects research may qualify for an exemption if

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, including research on regular and special education instructional packages and comparisons among instructional techniques(45 CFR 46.101(b)(1)).

(2) Research involving the use of educational tests, survey procedures or observation of public behavior, unless: information obtained is recorded in such a fashion that individuals can be identified and disclosure of the human subjects' responses outside the research could place the subjects at risk of criminal/civil liability and/or damage subjects' financial standing, employability, or reputation (45 CFR 46.101(b)(2)).

(3) (i)Research involving public officials or (ii) collection of personally identifiable information for which federal statutes require permanent confidentiality (45 CFR 46.101(b)(3)).

(4) Research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if: these data sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects (45 CFR 46.101(b)(4)).

(5) Research and demonstration projects approved by public agency heads and designed to study, evaluate, or otherwise examine public benefit or service programs (45 CFR 46.101(b)(5i)).

(6) Taste or food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed or all ingredients are at or below safe levels set by the FDA(45 CFR 46.101(b)(6)).

2. Expedited Review

Any member of the IRB may conduct an expedited review. In reviewing the research, the reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. When conducting an expedited review, the designated reviewer(s) has the authority to act on behalf of the IRB with the exception of disapproving the research. During the initial review process, questions may arise that require the investigator to provide additional information or clarification about the protocol. Questions developed during the initial review are communicated to the investigator via electronic or standard mail or by telephone after application submission. Upon receipt and acceptance of by the IRB representative(s) of the investigators response, approval to conduct the research is communicated to the investigator by standard mail or electronic correspondence. IRB members are informed of initial and continuing review and protocol modifications reviewed using expedited procedures at the appropriate convened committee meeting.

To determine if the research is eligible for an expedited review, please review the following federal requirements for expedited review:

a. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

b. The categories in this list apply regardless of the age of subjects, except as noted.

c. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

d. The expedited review procedure may not be used for classified research involving human subjects.

e. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

f. Expedited Research Categories

(1) Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excrete and external secretions, including uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) 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, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) 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 who are in good health and not pregnant. In addition, SJSU requires that any blood withdrawal procedure in the classroom or research must be performed by a person certified by the Student Health Service of SJSU. "Certified" refers to a person who can satisfactorily draw blood as decided by the Health Center's Director or his designee.

(5) Collection of both supra-and sub-gingival 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.

(6) Voice recordings made for research purposes, such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens if these data sources are not publicly available or the information is recorded

by the investigator in such a manner that subjects can be identified, directly or through identifiers linked to the subjects.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

3. Convened Committee Review

If the research is not eligible for an exempt or expedited review (e.g., involves more than minimal risk; an experimental design; subjects considered to be vulnerable [children, prisoners, cognitively impaired]; and/or deception) the protocol must be reviewed by the convened IRB membership at the monthly meeting. Full review will take place with a quorum of the IRB, defined as a majority of the total membership, including at least one member whose primary concerns are in a nonscientific area. Research protocols shall be distributed to the full membership at least one week in advance of the scheduled meeting. A protocol shall be approved if it receives the approval of a majority of those members present at the meeting. A primary reviewer is identified to present a specific protocol to other members in attendance. Following presentation and discussion, the committee will vote on a motion to either: 1) approve the protocol as it stands; 2) request revisions to the protocol to secure approval; 3) request that additional information be provided prior to further review by the convened committee; or 4) disapprove the protocol.

The IRB shall approve research if:

a. Risks to subjects are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk, and whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.

b. Risks to subjects are reasonable in relation to anticipated benefits from the research.

c. Selection of subjects is equitable, considering the purpose of the research, the setting, and the population from which subjects will be recruited.

d. Subjects are fully informed of their rights and of the potential risks and benefits of participation in the research.

e. Informed consent will be obtained from each prospective subject, as needed, and appropriately documented.

f. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, protecting the privacy of subjects, and maintaining the confidentiality of data.

4. Definitions of Risk

a. Psychological risk. Research that interrupts the normal activity of human subjects resulting in the immediate and/or long term stress that would not otherwise be experienced by the individual.

(1) Stress involves any situation that poses a threat to desired goals or homeostatic organismic conditions and thus places strong adaptive demands on the individual.

(2) Stress can be experienced during the actual research situation (immediate) and/or as a result of participation in research (long term).

(3) Some examples of situations that may result in stress are threat to self-esteem; exposure to noxious events; requests or demand for behaviors that are discrepant with an individual's values, morals and/or ethics; the requirement of excess physical effort.

b. Social risk to individuals. Social risk to individuals is the extent to which an individual subject is exposed to deprivation with respect to desired relations with and within both formal and informal social groups, or normal opportunities for such relationships. Such deprivations include (but are not limited to) derogatory labeling, overt hostile reactions by others, diminished access to otherwise available roles, negative effects on social standing or mobility, reduced opportunity for communication, lost or endangered membership in such groups.

c. Social risk to groups. Social risk to groups is the extent to which a subject formal or informal group, as a collective, is exposed to loss with respect to factors affecting the viability and vitality of the group. Such loss includes (but is not limited to) derogatory labeling, overt hostile reactions from the social environment, reduced access to resources, diminished ability to recruit and retain members, negative effects on morale and other aspects of internal cohesion and organization, violation of legally required procedures or risk of damage claims through civil action where there is corporate liability, reduced opportunities for communication, distortion of group activities relative to established group purposes and functions.

5. This policy exempts several classes of research from IRB review. Minimal risk comprises the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons (45 CFR 46.303 (d)). SJSU bases recognition of these exemptions on two assumptions: (1) the risk to participants in research is so minimal that required IRB review represents unwarranted intrusion into the research process; and (2) investigators (faculty, students or staff) understand, accept and will implement the principles of informed consent contained in this policy.

a. At SJSU, investigators who conduct exempt human subjects research are required to provide individual participants with reasonable and necessary information so they may form their own decision to participate (e.g., cover letter to a questionnaire) and/or secure permission to conduct human subjects research from participating institutions.

b. Proposals for external funding, sabbatical leave proposals, and master's theses/projects must include evidence that notice will be given and/or permission has been obtained.

D. Communication between the IRB and Investigators

1. Sample consent forms and/or cover letters shall be provided by the IRB through the IRB website.

2. Approvals, recommendations, restrictions, conditions or disapprovals shall be communicated to the research investigator in written form. Reasons for disapproval shall be set forth in detail with IRB recommendations for modification of the proposal.

3. All changes to a protocol in response to IRB recommendations must be made in writing.

4. Registration

a. Exemption is not the same as exclusion. Investigators must register with the IRB the classes of human subjects research cited in section VI.C.1.f, even though they are exempt from IRB review mandated by federal regulations

b. Registration forms are available through the IRB website and in the Graduate Studies and Research Office.

(1) Registration is not complete until a positive response from the IRB has been received.

(2) The IRB reserves the right to evaluate the risk of human subjects research identified by investigators as exempt and to require formal protocol review if risk is greater than minimal and it is deemed that expedited or full review is required.

5. Appeal Procedures

a. If a research investigator believes that his/her protocol has been disapproved because of incorrect, unfair, or improper evaluation by the
IRB, s/he may appeal to the IRB Chairperson.

b. The research investigator shall show cause in writing within 3 weeks after the negative decision as to why the IRB decision should be reversed.

c. The appeal shall be considered by a full committee review.

6. Complaint Review Procedures

a. Complaints about failure to protect human subjects participating in research activities covered by this policy shall be made in writing to the IRB Chairperson or to the Associate Vice President for Graduate Studies and Research.

b. Upon receipt of a complaint, the IRB Chairperson and one IRB member shall investigate the complaint by meeting with appropriate individuals and shall make a report with recommended action to the full IRB and to the AVP for Graduate Studies and Research. If the report includes recommendations to modify or terminate the activity, the Chairperson shall convene the IRB no later than the next scheduled meeting to discuss the complaint and all other pertinent information. The complainant and the involved research investigator shall be invited to appear at this meeting. After hearing all the evidence and addressing all appropriate questions, the IRB may decide to affirm the appropriateness of the activity, to request modification(s) or to terminate the activity.

c. The IRB decision shall be communicated to the complainant, the research investigator, and the AVP for Graduate Studies and Research in writing.

E. IRB Records and Reports

1. The IRB shall prepare and maintain adequate documentation of IRB activities.
Records of specific human subjects research activity shall be maintained for three years after termination of the last IRB approval period for the activity.
Records shall be accessible for inspection and copying by authorized representatives of Department of Health and Human Services (DHHS) at reasonable times and in a reasonable manner, or shall be copied and forwarded to DHHS when requested by authorized DHHS representatives. Records shall include the following:

a. Current IRB membership and operating procedures.

b. Copies of all human subjects research proposals reviewed, with all pertinent materials that accompany the proposals, progress reports, and any reports of injuries to human subjects.

c. Minutes of IRB meetings in sufficient detail to show names of attendees, actions taken with the votes specified, basis for requiring changes in or disapproving human subjects research, summaries of discussions re controversial issues and their resolution, and dissenting reports or opinions. If any member has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.

d. Reports of continuing review activities.

e. Copies of all IRB correspondence.

2. IRB shall report promptly to the Office for Human Research Protections these matters of information:

a. Changes in IRB membership.

b. Any serious or continuing noncompliance by research investigators with the requirements of the IRB

c. Any serious or continuing noncompliance by SJSU or its agencies with the requirements of this policy

d. Injuries to human subjects (also known as Significant Adverse Events, SAE)

e. Suspension or termination of IRB approval (with a statement of reasons for IRB action).

3. The IRB shall submit to the Office for Human Research Protections for approval of significant changes in SJSU policies or procedures.

F. Fundamentals of Informed Consent

This section (and section G following) deal with informed consent. First normal informed consent procedures are outlined, followed by a variety of specialized circumstances, and then finally in Section G Alternative Consent Procedures are outlined.

1. It is the responsibility of the investigator to obtain and document legally effective informed consent from the subject or his/her legally authorized representative, to ensure that no human subject will be involved in the human subjects research prior to obtaining the consent, and to maintain such documentation for three years.

a. Informed consent should be secured in the native language of the subject or subject's legally authorized representative, if English is not readily understood. At SJSU, translations in any language other than English shall be verified.

b. No consent form may contain language through which the subject is made to waive or appear to waive any legal rights, or to release the research investigator, the sponsor, SJSU or its agents from liability for negligence.

c. The consent form shall be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate.

2. The basic elements of informed consent:

a. A statement that the study involves human subjects research, a clear explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

b. A description of any reasonably foreseeable risks or discomforts to the subject.

c. A description of any benefits to the subject or to others which may reasonably be expected from the research.

d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

f. For human subjects 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.

g. An explanation of whom to contact for answers to pertinent questions about the research subject's rights, and whom to contact in the event of a research-related injury to the subject.

h. A statement that Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3. Additional elements of informed consent that may be required by the IRB:

a. A statement that the particular treatment or procedure has risks to the subject which are currently unforeseeable.

b. Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent.

c. Any additional costs to the subject that may result from participation in the research.

d. The consequences of a subject's decision to withdraw from participation and procedures for orderly termination of participation by the subject.

e. A statement that significant new findings developed during the course of the research will be provided to the subject if they relate to the subject's willingness to continue participation.

f. The approximate number of subjects involved in the study.

4. Research investigators shall be responsible for ensuring that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or his/her legally authorized representative, unless the IRB specifically waives this requirement. Each person signing the written consent form shall receive a copy of that form. The consent form may be read to the subject or his/her authorized representative or may be presented orally (with a witness who shall sign a written summary of the oral presentation).

5. IRB shall assess the need for a written consent form. Under appropriate conditions the IRB may waive this requirement IF (1) the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context [except when vulnerable populations are to be used, e.g., children] or (2) the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality (see below for waiver conditions). If written consent is waived, the IRB will require the research investigator to provide subjects with a written statement (e.g., a cover letter to a questionnaire) that outlines the risks and benefits of research, confirms that participation is voluntary, and identifies individuals who may be contacted for questions or alleged injury.

6. Informed Consent Guidance

a. Consent Purpose. The Office for Human Research Protections (OHRP) states that “informed consent is one of the primary requirements underpinning research with human subjects; it reflects the basic principle of respect for persons." Informed consent is the knowing consent of an individual or his/her legally authorized representative, which is obtained without undue inducement or element of force or coercion. Obtaining informed consent is a process in which an individual is given enough information about a study to make a decision about whether to participate in the research. The consent process involves discussing the details of study participation with a knowledgeable member of the research team as well as reading, understanding and signing an informed consent form to document that the process has occurred and agreement to participate.

b. Consent Process and Procedures. The following procedures should occur during the informed consent process (45 CFR 46.116):

(1) The prospective subject is given adequate information to make an informed decision about participating in the proposed study.

(2) The nature and expectations of the research including risks and benefits is explained.

(3) The study is presented in a language that is clear and understandable.

(4) The individual receives answers to questions about the study.

(5) The study is explained in an appropriate setting and with enough time conducive to good decision-making.

(6) The prospective subject comprehends the information and can make a choice about whether they want to participate.

(7) The prospective subject understands that he/she retains the right to refuse or withdraw from the study at any time without penalty.

(8) The prospective subject and/or the parent or guardian is given copies of the approved consent form(s).

(9) The subject (or the parent/guardian when relevant) is provided with a copy of the Research Participant's Bill of Rights to sign when the research involves medical experimentation.

(10) The investigator retains the signed copies of the consent document and the Research Participant's Bill of Rights (when applicable) for three years.

7. Components of a Consent Form. The following information must be included in an informed consent document (45 CFR 46.116(a,b)):

a. A statement that the subject is being asked to participate in a research study.

b. The names and degrees of all investigators involved in the study as well as the department and institution with which the investigator(s) is affiliated. When the investigator is a student, the person supervising the research is included.

c. An explanation of what the study is designed to determine or assess using language that is clear to the target audience.

d. The number of subjects being recruited for this study and the eligibility criteria used to identify prospective participants.

e. The procedures that the subject will be asked to follow.

f. The location where the research will be conducted, the amount of time required and the expected duration of the subject's participation.

g. A description of any risks or discomforts the subjects might encounter as a result of participation.

h. Provisions made to address risks or discomforts.

i. A statement to describe potential benefits to science and society that may result from this research as well as any benefits the subjects can expect as a result of participating in the study.

j. The extent, if any, to which confidentiality of records identifying the subject will be maintained and the procedures for using and storing data.

k. A description of any incentive offered and what is required to obtain the incentive. If the subject is offered a payment, state the amount, formula for prorating should the subject or investigator choose to discontinue participation, and when payment will occur. If an incentive is not offered, state that the participant will not be paid to participate in this study.

l. Any procedures which are experimental.

m. When applicable, appropriate alternative procedures or courses of treatment that might be available or advantageous.

n. Contact information of study personnel and IRB should the participant have questions or concerns about participation in the research.

o. A statement that the subject's participation in the study is voluntary and that he/she can withdraw consent and stop participation at any time without penalty or loss of benefits allowed.

p. Unless a waiver of documentation of consent has been granted (see Section VI.G.4. below on “Waiver of Written Consent”) include a signature and date line for the participant and the investigator (or individual administering the consent form) to complete. Label the signature lines as “subject” and “investigator” (or “study representative if the individual administering the consent form is not the principal investigator.) In addition, include space for the subject and the investigator (or individual administering the consent form) to print their name.

8. Structure of a Consent Form. The following points must be followed to ensure that the subject understands the nature and purpose of the research in which they are being asked to participate:

a. The consent should be written in 6th to 8th grade reading level avoiding technical jargon.

b. The consent document should be written in the second person (using the "you" pronoun).

c. Legible font size is used based on population targeted (11 or 12 point minimum).

d. Use of clear paragraph/section headings to allow the potential subject ease of access to specific study information.

e. Double spacing is used between paragraphs.

9. Obtaining Parental Permission (45 CFR 46.408 (b)). Parental permission is required when recruiting children or minors as subjects in research. In California, a minor is identified as a person under the age of 18 years. Parental permission must be obtained in advance of enrolling a minor subject into a study. The Informed Consent format is used when developing a Parental Permission form.
Text should reflect the activities that the child (and the parent, if they are also considered a subject) will be asked to participate in as a research subject. If the consent form is being developed to obtain parental permission only, the signature line is labeled "Parent or Guardian of Subject." The child subject's name is also printed to identify the child for whom they are giving permission.

10. Obtaining Assent/Dissent from Minors (45 CFR 46.408(a)). In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with section 9 above.

11. Short Form Written Consent (45 CFR 46.117(b)). The regulations also allow for consent to be documented by signing a "short form" that states only that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, the
IRB will approve a written description of the consent statement that is orally presented to the prospective subject. In addition, a witness to the oral presentation is required. Following the oral presentation, the prospective subject/legal representative will sign the "short form" if he/she decides to participate in the research. The witness verifies the consent process by also signing the "short form" and the consent statement that is presented orally to the subject. A copy of the consent statement is then given to the subject or the representative, in addition to a copy of the signed "short form."

12. Consent Translation. Both DHHS regulations (45 CFR 46.116) and FDA regulations (21 CFR 50.20) require that informed consent be obtained in language understandable to the subject (or the subject's legally authorized representative), and documented in writing (46.117 and 50.27, respectively).
Non-English speaking persons must be presented with and sign a consent form that is written in their primary language. The investigator must provide the IRB with a language appropriate translated consent document for review and approval prior to recruiting subjects. It is recommended that the investigator

secure IRB-approval of the English consent document prior to translating the consent form. The IRB does not require that a certified translator perform the document translation. But the IRB does require verification of the translation. The verification may be provided by a member of the Department of Foreign Languages, an individual who has a bachelor's degree in that language, an individual who has received an education through secondary school with that language as the language of instruction, or from a certified translator. While the IRB does not verify the accuracy of the translated consent document the investigator must provide assurance to the IRB that the consent or assent form has been adequately translated. The IRB recommends Informed consent should be secured in the native language of the subject or subject's legally authorized representative, if English is not readily understood (see also G. 4. a. below).

G. Alternative Consent Procedures (45 CFR 46.116 (6c)). The IRB may approve a consent procedure that does not include or changes the basic consent requirements or even waive the requirement to obtain informed consent when the following applies and can be documented:

1. 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: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

3. The IRB may also approve a consent procedure, which does not include or alters the basic consent requirements or even waive the requirement to obtain informed consent when the following conditions apply and can be documented:

a. The research involves no more than minimal risk to the subjects;

b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

c. The research could not practicably be carried out without the waiver or alteration;

Please note: The regulations referenced do not preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

4. Waiver of written consent. The IRB will review each request individually, considering all aspects of the particular study. Requests should be thoroughly explained and include a description of the alternate method of obtaining consent, such as providing notice of informed participation (e.g., a cover letter and/or opening statement in a telephone survey). If oral consent is planned, the text of the statement must be submitted. The requirement to obtain written consent from human subjects may be waived by the IRB in situations such as the following:

a. Subjects are from cultures that utilize oral rather than written traditions.

b. Written consent might greatly hinder rapport building in cross-cultural and/or cross-ethnic research or in oral history recordings.

c. The subject has sought participation in an adequately publicized research activity (e.g., subject has responded to a notice posted on a public bulletin board) in which the nature of the risks and benefits are clearly explained.

d. The subject comes from a class of people well able to protect themselves, such as public officials, university administrators, medical or legal professionals, and is being questioned on matters pertinent to his/her profession and/or job-related responsibilities.

e. The research is performed using existing data held by a third party and no identification will be possible.

f. Obtaining written consent would be impossible, such as with telephone surveys.

5. Obtaining Consent in Exempt Research. A signed consent form is not usually required for exempt research although investigators should include the following information so that informed consent can be obtained. The investigator will provide adequate information about the research to potential subjects so that an informed decision can be made. The investigator can deliver this information verbally or both verbally and in writing. The appropriate mode of delivery will depend on administration procedures. The consent statement will include the information needed for a participant to make a decision regarding participation.
The statement will be written in a language easily understood by the target audience. When applying for IRB review, the information that will be presented to the potential subject is provided. Obtaining consent in exempt research should include the following information:

a. Investigator's name, institutional affiliation, academic status and contact information.

b. Study purpose.

c. A brief description of what subjects will be asked to do and the time involved.

d. That participation is voluntary and that the person may withdraw at any point.

e. How data will be recorded and maintained as well as who will have access.

f. A description of incentives/compensation offered or costs that may be incurred.

APPENDIX

ADDITIONAL RELEVANT SJSU POLICY DOCUMENTS:

F90-4: “POLICY FOR PROTECTION OF HUMAN RESEARCH SUBJECTS; ETHICS; INSTITUTIONAL REVIEW BOARD (IRB)’

http://www.sjsu.edu/senate/f90-4.htm

S99-11: “Conflict of Interest Policy for Principal Investigators”

http://www.sjsu.edu/senate/s99-11.htm

F00-1: Policy Recommendation
“Modification to F90-4, Policy For Protection of Human Research Subject: Ethics: Institutional Review Board”

http://www.sjsu.edu/senate/F00-1.pdf

F05-1: SENATE MANAGEMENT RESOLUTION
“CREATING AN INSTITUTIONAL REVIEW BOARD-HUMAN SUBJECTS TASK FORCE”

http://www.sjsu.edu/senate/SM-F05-1.pdf

S05-3:
POLICY RECOMMENDATION
“INSTITUTIONAL REVIEW BOARD-HUMAN SUBJECTS TRAINING FOR INVESTIGATORS”

http://www.sjsu.edu/senate/S05-3.htm

FEDERAL GUIDELINES

Code of Federal Regulations, TITLE 45: PUBLIC WELFARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, PART 46: PROTECTION OF HUMAN SUBJECTS

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

and interpretive document/guidelines:

http://www.hhs.gov/ohrp/irb/irb_guidebook.htm