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

Legislative History:

Document dated October 31, 1990.

At its meeting of October 22, 1990, the Academic Senate approved the Policy Recommendation, "Policy for Protection of Human Research Subjects," presented by George Moore for the Curriculum and Research Committee. By this Policy, S 79-18 is superseded.

ACTION BY THE UNIVERSITY PRESIDENT:

"Approved and Accepted as University Policy. Effective immediately." Signed: Gail Fullerton, October 31, 1990.

SAN JOSE STATE UNIVERSITY

POLICY FOR PROTECTION OF HUMAN RESEARCH SUBJECTS

I. Principles, Applicability, and Institutional Policies.

A. Principles

SJSU acknowledges and accepts responsibility for protecting the rights and welfare of human subjects in research. SJSU is guided by the ethical principles regarding all research involving humans as subjects as set forth in the National Research Act (Public Law 93-348, amended in 1985) and implemented in the Code of Federal Regulations, 45 CFR 46. Where other social and medical bodies (such as AMA, ANA, APA) have established more stringent principles, those will be applied. Where research takes place in foreign countries, comparable foreign statutes which provide additional protections for human subjects may be substituted for the provisions of federal regulations cited above.

SJSU will also be guided by the following principles:

1. No human subject is to be exposed to unreasonable risk to health or well-being whether physical, psychological or social.

2. Commensurate with the principles of protection of human subjects, the procedures for assessing and minimizing risk to human subjects shall respect and protect the academic freedom of the faculty and students in their pursuit of knowledge.

3. The risks to an individual must be outweighed by the potential benefit.

4. The identity and personal privacy of the human research subject(s) and the confidentiality of information received shall be protected.

5. The nature of the research, the procedures to be followed, and the possible risks involved must be carefully and fully explained to the subject, parent or guardian. There must be assurance that the explanation has been understood and consent in writing obtained without duress or deception. Where research presents potential physical harm, the subject(s) must be informed whether there is financial protection for them in the event that they are injured.

6. Voluntary and informed participation is essential in all projects. No information concerning a project may be withheld from a potential subject to increase the willingness of the subject to participate in the project.

7. A subject may request at any time that participation in the research be terminated, and that request shall be honored promptly and without prejudice.

8. It shall be the responsibility of the individual investigator to decide when s/he does not have adequate knowledge of the possible consequences of the research, or of research done under his/her direction. When in doubt, the investigator shall obtain the advice of others who do have the requisite knowledge.

9. Research involving populations with diminished capacity to evaluate potential risks and therefore provide informed consent- such as the mentally or physically infirm, children, prisoners -- may require additional precautions to assure protection of their rights as human subjects.

10. When research takes place in a foreign country or in a minority community culture, the investigator must consider the ethical principles of that culture in addition to the principles listed herein.

11. Whenever medication or operative procedures are used or there are exposures to hazardous environmental conditions, the research must be performed under medical protection and supervision.

12. Potentially hazardous research procedures must be preceded by laboratory and animal experimentation or other scientifically established procedures that offer reasonable assurance that the safety of the human subject will be preserved.

13. Remuneration may be offered to an individual for the time involved in a study provided that under the circumstances the remuneration is not so large as to constitute an undue or unreasonable inducement.

B. Applicability

1. 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) using SJSU's time, facilities, resources and/or students. Student research must be sponsored by a member of the faculty.

2. Research involving human subjects covered by this policy pertains to systematic investigation (including research development, testing and evaluation) involving individuals about whom an investigator obtains data through intervention or interaction with the individual(s) or obtains identifiable private information. 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.

a. THERE IS HUMAN SUBJECT INVOLVEMENT:

(1) when human beings are asked to participate physically in an activity or to donate their tissue, organs, fluids and other bodily material;

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

(3) when 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.

b. THERE IS NO HUMAN SUBJECT INVOLVEMENT:

(1) 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;

(2) 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;

(3) 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.

(4) when people are asked to provide information or act as a source of information about their organization, profession or community as a function of their job, profession or standing in the community.

3. Policies and procedures presented here are not applicable to courses that deal with established research methodology and are identified as research practica. Numerous 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 with a better understanding of social, educational, or psychological processes, and/or with an opportunity to practice the same methods of observation common to the discipline in which the experience is offered. Any potential risks that might be incurred by human subjects in these practice are the responsibility of the instructor.

The instructor in 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 in this document. 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.

4. Policies and procedures presented here are applicable to any student-initiated and/or student-conducted research that does not fall under the heading of a research practicum, and that uses human subjects. This includes all undergraduate independent study, graduate courses in which the student is the initiator of the research, and graduate projects and/or theses. The instructor in such courses may mandate research as part of the course requirements; however, the topic of research and the involvement of human subjects is developed by the student and is executed as an independent project within general course guidelines or with advice from the instructor.

5. Research exempt from formal review by federal guidelines, but whose conduct also requires respect for individual rights and welfare, is addressed in Section II.B.9 below.

C. Institutional Policies

1. 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. 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. 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.

2. 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. 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. The IRB shall require documentation of informed consent if human subjects will be exposed to risk. The IRB has the authority to observe or have a third party observe the consent process and/or the research.

3. The IRB shall conduct continuing review of research procedures involving human subjects at intervals appropriate to the degree of risk. Investigators shall inform the IRB when such research extends beyond one funding/academic year.

4. 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 II.B.9. below will require review by the IRB if it involves these vulnerable populations as human subjects.

5. 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, SJSU may accept the written review of an IRB in another institution established under assurance of compliance with federal guidelines.

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

II. Description of Procedures

A. Institutional Review Board (IRB)

1. SJSU has delegated administrative authority for the protection of human subjects to the Associate Academic Vice President for Graduate Studies and Research (AAVP/GS&R), who is an ex-officio member of the IRB. The AAVP/GS&R will maintain IRB files, coordinate meetings, and process protocol reviews. The IRB at SJSU is a ten-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 Protection from Research Risks, DHHS.

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 two physicians.

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

B. Protocol Review Procedures

1. Prior to data collection, any SJSU employee or student planning to do research involving human subjects shall submit two copies of a research protocol to the IRB for review. Student research must be sponsored by a member of the faculty. All required forms are available in the office of the AAVP/ GS&R.

2. The protocol shall provide a complete description of 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 insure that pertinent regulations are observed.

3. Protocols shall be assigned to individual IRB members on a rotating basis to assess risk (see Appendix A).

a. An expedited review process is permissible when research poses no more than minimal risk to human subjects and/or there are minor changes in previously approved research during the year for which approval was granted. 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. The types of research for which expedited review is authorized are specified in Appendix B.

b. 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.

4. 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 (see Appendix C for fundamentals of informed consent, Sample A for format).

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

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 Appendix D for possible 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 (see Sample B for format).

6. Sample consent forms and/or cover letters shall be provided by the IRB.

7. 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.

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

9. This policy exempts several classes of research from IRB review. 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 Appendix C of this policy. At SJSU, investigators who conduct exempt 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, see Sample B for format) and/or secure permission to

conduct research from participating institutions. 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.

Investigators must register with the IRB the following classes of research, even though they are exempt from IRB review mandated by federal regulations:

a. 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.

b. Research involving the use of educational tests, survey procedures, interview procedures, or observations of public behavior unless information is recorded in such a fashion that individuals can be identified and disclosure of human subjects' responses outside the research could place subjects at risk of criminal/civil liability and/or damage subjects' financial standing, employablity or reputation.

c. Research involving public officials or collection of personally identifable information for which federal statutes require permanent confidentiality.

d. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens if these sources are publicly available and no individual identifications can be made.

e. Research and demonstration projects approved by public agency heads and designed to study, evaluate or otherwise examine public benefit or service programs.

f. Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed or if all ingredients are at or below safe levels set by the FDA.

Registration forms are available in the Graduate Studies Office. IRB reserves the right to evaluate the risk of research identified by investigators as exempt and to require formal protocol review if risk is greater than minimal.

10. 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 14 working days after the negative decision as to why the IRB decision should be reversed.

c. The appeal shall be considered by a full committee review. The decision of the IRB following the

reconsideration shall be final.

10. 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 Academic 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. If the report includes recommendations to modify or terminate the activity, the Chairperson shall convene the IRB in a timely fashion 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 and the research investigator in writing.

C. IRB Records and Reports

1. The IRB shall prepare and maintain adequate documentation of IRB activities. Records of specific 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 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 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 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 Protection from Research Risks these matters of information:

a. Changes in IRB membership or significant changes in SJSU policies or procedures.

b. Any serious or continuing noncompliance by research investigators with the requirements of the IRB, injuries to human subjects, unanticipated problems, and suspension or termination of IRB approval (with a statement of reasons for IRB action).

APPENDIX A

DEFINITIONS OF RISK

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.

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 labelling, 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.

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 labelling, 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.

APPENDIX B

CATEGORIES OF RESEARCH ELIGIBLE FOR EXPEDITED REVIEW

1. Collection of hair and nail clippings, in a nondisfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

2. Collection of excrete and external secretions, including uncannulatet 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.

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.

APPENDIX C

FUNDAMENTALS OF INFORMED CONSENT

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 insure that no human subject will be involved in the 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 by the Foreign Languages Department or equivalent professionals.

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 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 forseeable 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 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 unforseeable.

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 insuring 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).

APPENDIX D

WAIVER OF WRITTEN CONSENT

The requirement to obtain written consent from human subjects may be waived by the IRB in situations such as the following:

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

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

3. 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.

4. 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.

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

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

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.

INSTRUCTIONS FOR REQUESTING AN EXEMPTION FROM HUMAN SUBJECTS REVIEW

San Jose State University policy exempts several classes of research from IRB review. 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 Appendix C of the "San Jose State University Policy for Protection of Human Research Subjects". At SJSU, investigators who conduct exempt 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 research

from participating institutions. 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.

San Jose State University policy requires that investigators conducting research which is exempt from review must register their project with the IRB.

If you believe your proposed research project qualifies under one or more of the exempt categories listed on the request form, you may submit a request for Exemption From Human Subjects Review. Complete the attached form and deliver it to the Graduate Studies Office.

REQUEST FOR EXEMPTION FROM HUMAN SUBJECTS REVIEW

Name:

Phone:

Address:

SJSU Faculty:

SJSU Staff:

SJSU Graduate Student:

SJSU Undergraduate Student:

Not affiliated with SJSU:

If SJSU student, name of faculty advisor or instructor:

Title of Project:

Abstract of Project:

Description of Subjects:

Description of Data Collection Procedures:

Category of Exempt Research:

(see list on back of page)

ACTION:

Request Approved:

More Info Requested:

IRB Review Required (attach protocol):

Reviewer:

Date:

CATEGORIES OF EXEMPT RESEARCH

a. 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.

b. 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.

c. Research involving public officials or collection of personally identifiable information for which federal statutes require permanent confidentiality.

d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available and no individual identifications can be made.

e. Research and demonstration projects approved by public agency heads and designed to study, evaluate, or otherwise examine public benefit or service programs

f. 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.