HUMAN SUBJECTS PROTECTION IN RESEARCH

Definition: The California State University, San Marcos (CSUSM) Institutional Review Board (IRB) implements a review process established within the Code of Federal Regulations (CFR) to ensure that human subject research complies with federal regulations, institutional policies, and ethical standards. The IRB serves to protect the rights and ensure the safety of people involved as participants in research. To this end, the IRB reviews research when procedures are proposed to obtain information from a living individual, for example, through the use of survey, interview, observation, ethnography, experimentation, or the analysis of human tissue, etc. Research involving human subjects must be reviewed and approved by the IRB prior to initiating the study.

Authority:


B. All relevant application forms and sample documents are available online at www.csusm.edu/irb.

C. For guidance, concerned parties should consult (1) the Nuremberg Code, (2) the Belmont Report, and or 3) the Office for Human Research Protections (OHRP). Links to these documents are provided on the CSUSM IRB website. In addition, many professional organizations have their own policies on the protection of human subjects.

D. Where discrepancies occur, this policy shall be bound by the Code of Federal Regulations’ Protection of Human Subjects, 45 CFR Part 46 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)

Scope: The purpose of this policy is to provide a comprehensive human subjects policy that reflects current federal mandates for the protection of human subjects and ensures ethical research practices. This policy applies to all CSUSM faculty, administrators, staff, and students whenever they are supervising or conducting research involving human subjects, regardless of whether the subjects are members of the CSUSM community. This policy applies to human subjects research conducted at other institutions by CSUSM faculty, staff, and students, even if that institution has its own review process. Researchers not affiliated with CSUSM, but conducting research with CSUSM faculty, staff, students and/or alumni, must also be approved by this IRB.

All research involving human subjects or personal data must be in compliance with this policy, including research classified as exempt. CSUSM cannot accept responsibility for research conducted in violation of University policy and without required review and approval.

Approved by the Academic Senate 05/02/2007
HUMAN SUBJECTS PROTECTION IN RESEARCH

Effective Date: 8/4/2008

Karen S. Haynes, President

EmiHy F. Cutrer, Provost and Vice President for Academic Affairs

Approval Date

Implemented: 8/4/2008

Approved by the Academic Senate 05/02/2007
I. DEFINITIONS (CFR 46.102)

A. General Definitions

1. **IRB** in this document means the California State University, San Marcos Institutional Review Board established in accord with and for the purposes expressed in this policy.

2. **IRB Application** refers to the Review and Consent forms that the researcher must submit for approval before the research begins.

3. **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

4. For the purposes of this IRB policy, **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes (e.g., pilot projects and service programs may include research activities).

5. **Research subject to regulation**, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity (e.g., Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (e.g., Wage and Hour requirements administered by the Department of Labor).

6. **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains either:
   a. Data through intervention or interaction with the individual, or
   b. Identifiable private information.

7. **Intervention** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject.

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

9. **Risk** means any physical, psychological, social, and/or economic effects that may arise as a result of the specified research.

10. **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

11. **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

12. **Certification** means the official notification by the institution to the supporting federal department or other funding agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by the IRB in accordance with an approved assurance.


14. **University** means California State University, San Marcos (CSUSM).

15. The **CSUSM Foundation** is a self-supporting auxiliary organization, recognized by the California State University and incorporated as a 501(c)(3) non-profit corporation, which generates and manages additional resources and assets in support of the University's existing and emerging programs.

16. **Federal Department or Agency Head** means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

**B. Additional definitions related to Children**

1. **Children** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

2. **Assent** means a child's affirmative agreement to participate in research. Failure to object should not, absent affirmative agreement, be construed as assent.
3. **Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research.

4. **Parent** means a child's biological or adoptive parent.

5. **Guardian** means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

**II. RESPONSIBILITIES AND COMPLIANCE**

A. CSUSM acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this policy statement. The institutional official specifically charged with this responsibility is the **Associate Vice President for Research** (AVPR). It is the responsibility of the AVPR, that office, and its staff:

1. To disseminate this policy and foster an atmosphere of respect for human subjects across the campus community.

2. To maintain the CSUSM Federal-wide Assurance (FWA) and comply with the requirements for documentation, reporting, and record maintenance.

3. To immediately report research-related problems to the appropriate funding agencies, and to work with the CSUSM Foundation in communicating with funding agencies with respect to necessary assurances and policies.

4. To provide administrative support to the IRB such as maintaining copies of all protocols, recording the minutes of IRB meetings, documenting IRB decisions, maintaining the IRB database, and other recordkeeping as specified in CFR 46.115. Said records shall be kept for a minimum of three years.

5. To work with the CSUSM Foundation and the IRB Chair to monitor changes in regulatory guidelines and to revise this policy accordingly.

B. It is the responsibility of the **IRB Chair** to convene meetings of the IRB, provide training for IRB members, oversee the reviewing of protocols, monitor changes in regulatory guidelines from federal departments and funding agencies, communicate IRB decisions to investigators, and provide opportunities for the campus community to be educated on the ethical treatment of human subjects.

C. It is the responsibility of **IRB members** to attend regularly convened meetings of the IRB, to review protocols as assigned in a timely manner, to know the federal guidelines on the protection of human subjects, to complete OHRP training before voting on or reviewing protocols, to participate in any other training necessary, and to act as a resource on issues pertaining to the protection of human subjects for members of the campus community.
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D. It is the responsibility of heads of departments, colleges, programs, units, etc. and/or appropriate management to bring the existence of this policy to the attention of their faculty, staff, and students.

E. Responsibility for the establishment and maintenance of acceptable ethical practice in research always remains with the individual investigator. The investigator is also responsible for obtaining training in the protection of human subjects as required by the CSUSM IRB and by any funding agency.

F. It is the responsibility of Supervising Faculty to help student investigators create a viable and sound IRB application. Supervising Faculty must provide continued support to the student to ensure that the student’s research is carried out in an ethical manner. The supervising faculty is responsible for assuring that human subjects are fully protected.

G. All research conducted by Student Investigators must have a faculty supervisor.

H. Additional Compliance Responsibilities

1. Compliance with this policy requires compliance with pertinent federal laws or regulations that provide additional protections for human subjects. (CFR 46.101(e))

2. This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects. (CFR 46.101(f))

3. This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research. (CFR 46.101(g))

4. When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, the more protective procedures (university or foreign institution or agency) must be followed. (CFR 46.101(h))

5. Federal funds administered by a federal department or agency may not be expended for research involving human subjects unless the requirements of this policy and the granting agency have been satisfied. (CFR 46.122)

III. IRB COMPOSITION (CFR 46.107)

A. The IRB shall be composed as follows:

1. The IRB shall have at least five faculty members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution as specified below in Sections III.B through III.G. Members shall be recommended by the Nominations, Elections, Appointments, and Constitution
Committee (NEAC) of the Academic Senate or, when needed to maintain compliance with federal regulations, appointed by the AVPR.

2. In addition there shall be:

a. one student representative recommended by Associated Students, Inc. (ASI);

b. one representative of the CSUSM Foundation,

c. at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution (CFR 45.107(d)) recommended by the Chair of the IRB and approved by majority vote of the committee.

3. The AVPR or designate shall act as the Institutional Official and the Human Protections Administrator. The AVPR is the only non-voting member.

B. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members (including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes) to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

C. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

D. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or persons with disabilities, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

E. The IRB shall make every effort to have a gender-balanced committee. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. (CFR 46.107b)

F. The IRB may not consist entirely of members of one profession.

G. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. (CFR 45.107(c))
H. An IRB member may not participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

I. The IRB may, using discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals shall not vote with the IRB.

IV. FUNCTIONS AND OPERATIONS OF THE IRB

In order to fulfill the requirements of this policy the IRB shall:

A. Conduct “Full Reviews” at convened meetings at which a quorum (i.e majority) of the voting members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of the quorum. (CFR 46.108(b))

B. Review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. (CFR 46.109(a))

C. Require that information given to subjects as part of informed consent is in accordance with the Informed Consent section of this document (Section VII). The IRB may require that information, in addition to that specifically mentioned in the Informed Consent section, be given to the subjects when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of subjects. (CFR 46.109(b))

D. Require documentation of informed consent or waive documentation in accordance with Sections VII.D and VII.E. (CFR 46.109(c))

E. Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. (CFR 46.109(d))

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

G. Under an expedited review procedure, have the review carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review and majority vote at a convened meeting of the IRB.
H. Keeping members advised of research proposals which have been approved under the expedited procedure.

I. Have Exempt Applications reviewed administratively and approved by the IRB Chair.

J. Conduct reviews of submissions on Minor Modifications of Approved Research according to the same methodology used for the original review. Reviews of Minor Modifications will not extend the approval period.

K. Forward any appeals to the IRB Chair for resolution. The IRB Chair may consult with the AVPR in responding to such appeals.

L. The IRB does not have the authority to approve research retrospectively.

V. IRB APPROVAL OF RESEARCH

A. Criteria For Approval (CFR 46.111)

In order to approve research covered by this policy the IRB shall determine that all of the following federal requirements are satisfied:

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

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required. (See Informed Consent, Section VII).

5. Informed consent will be appropriately documented, in accordance with, and to the extent required. (See Documentation of Informed Consent, Section VII.D).

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

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

8. When subjects are minors, adequate provisions are made to secure child assent and parental consent as required in Section VII.I.C.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as students, employees, children, prisoners, pregnant women, persons with disabilities, or persons who are economically or educationally disadvantaged, additional safeguards must be included in the study to protect the rights and welfare of these subjects. See Additional Protections (Section VII.I) for requirement on research involving certain populations.

B. Review by Institution (CFR 46.113)

Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB.

C. Suspension or Termination of IRB Approval of Research (CFR 46.113)

The IRB shall have authority to develop and implement a written procedure for suspending or terminating approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the funding department or agency as appropriate.

D. Cooperative Research (CFR 46.114)

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human. With approval, as appropriate, of the funding agency, an institution participating in a
cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

VI. RESEARCH NOT REQUIRING IRB REVIEW

A. Research Conducted as a Normal Part of a CSUSM Course

Research Training courses and classroom curricula projects in which students conduct research involving human subjects do not usually require review. This includes student feedback (evaluation) surveys, most classroom assessment techniques, and most exercises under the direct supervision of the instructor. Research training courses and classroom curriculum projects in which students conduct research involving human subjects need not be reviewed by the IRB if all four of the following conditions are satisfied:

1. the project(s) involves no more than minimal risk to subjects; and

2. the project(s) do not involve vulnerable populations; and

3. the results will not be presented, published or distributed outside the classroom and/or institutional setting; and

4. where subjects remain anonymous.

Activities that are part of coursework but do not meet these conditions, because they may be published and/or may not be anonymous, require a CSUSM Course, Exempt (VII.A.3), or Expedited Review (VII.B.4), as appropriate.

B. Program Evaluation, Needs Assessment and Quality Control

Studies conducted for the purposes of program assessment, 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 generalized knowledge or for publication and presentation are not subject to IRB review.

VII. CATEGORIES OF REVIEW CONDUCTED BY THE IRB

The following sections describe the categories of review, as stipulated by federal guidelines. Special considerations are required for prisoners, pregnant women and fetuses, children and wards of state (see Section VII.I.)

A. Exempt Review (CFR 46.101(b))

Unless otherwise required by law, federal department or agency head, or other organization, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy. A “Request for Exempt Status” must be submitted for review by the IRB Administrator and approved by the IRB Chair.
The following are categories of Exempt research:

1. 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.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior only if:
   a. research is completely anonymous (no links or identifiers to subjects) AND
   b. there is NO risk of disclosure of the human subjects' responses outside the research which could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation
   OR
   c. the human subjects are appointed public officials or candidates for public office
   OR
   d. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

3. Research training courses and classroom curriculum projects in which students conduct research involving human subjects:
   a. That involve no more than minimal risk to subjects,
   b. where subjects remain anonymous,
   c. and where results may be published, presented, and/or distributed outside the classroom or institutional setting.

A CSUSM class form may be used in lieu of individual exempt forms for each student as long as any presentations are specifically labeled as class projects.

4. Research and demonstration projects which are conducted by or subject to the approval of the federal department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or
alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

6. Taste and food quality evaluation and consumer acceptance studies if:
   a. wholesome foods without additives are consumed,
   b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or
   b. agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

There are several exceptions to the above policy on exemption.

1. Prisoners: The above exemptions do not apply to research involving prisoners.

2. Children: The exemption in Section VIII.A.2 does not apply to research with children where the researcher either a) participates in activities being observed, or b) conducts surveys, interviews or otherwise engages in direct interaction with children except for educational tests and normal educational practices which remain exempt.

**B. Expedited Review (CFR 46.110)**

Expeditied reviews are conducted for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

Use the following criteria to determine an expedited review:

1. Research appearing on the list of specific criteria below and found by the reviewer(s) to involve no more than minimal risk.

2. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

3. Continuing Reviews of research if:
   a. previously approved under the expedited method and no adverse affects have been identified.
b. previously approved by the full (convened) committee only where items 8 or 9 in the specific list of categories below apply.

4. Research training courses and classroom curriculum projects in which students conduct research involving human subjects:

a. That involve no more than minimal risk to subjects,

b. where subject **may not be anonymous** but where confidentiality can be assured, and

c. where results **may be published**, presented, and/or distributed outside the classroom or institutional setting.

A CSUSM Course & Instructional IRB Review form may be used in lieu of individual exempt forms for each student as long as any presentations are specifically labeled as class projects.

**Specific Categories for Expedited Reviews**, (63FR60364-60367, Nov. 9, 1998):

1. Research, if not exempt, on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

2. Collection of data from voice, video, digital, or image recordings made for research purposes.

3. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

4. Prospective collection of biological specimens for research purposes by noninvasive means.
5. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

6. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. (45 CFR 46.101(b)(4)). This listing refers only to research that is not exempt.)

7. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

8. Continuing review of research previously approved by the convened IRB as follows:
   a. where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

C. Full Review

If the research is not eligible for an exempt or expedited review, the protocol must be reviewed by the convened IRB meeting as a full review.
Any of the following criteria may determine a full review:

1. Research subjects at more than minimal risk.

2. Research involves subjects who are vulnerable to coercion or undue influence.

3. Confidentiality of a subject's responses cannot be assured.

4. Research involves the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subjects' financial standing, employability, insurability, or reputation.

5. Research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior) and the confidentiality of a participant's responses cannot be assured (e.g., audio or videotaped interviews, or a "key" which would allow someone to match a set of responses with a particular participant.)

6. Research involves prisoners, fetuses, pregnant women, the seriously ill, or adults who are mentally or cognitively compromised as subjects.

7. Research with children where research activity is outside of normal daily activities.

8. Research training courses or student research that may involve more than minimal risk to subjects or involve vulnerable populations.

D. Additional Considerations for Research Under Review

1. Applications and Proposals for Grants or Contracts Lacking Definite Plans for Involvement of Human Subjects (CFR 46.118).

   Certain types of applications for grants, cooperative agreements, or contracts are submitted to funding agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. However, except for research exempted or waived under CFR 46.101, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted when required, by the institution, to the funding agency.

2. Research is Undertaken Without the Intention of Involving Human Subjects (CFR 46.119).

   In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by the IRB, as provided in this policy. As appropriate, a
certification will be submitted, by the institution, to the funding agency, and final
approval given to the proposed change by the funding agency.

3. Consultants

The IRB is required to review all research conducted by or under the direction of an agent
of the institution unless the investigator is hired on his/her own time, does not utilize the
institution’s resources, and will not reference the institution in documents and
publications associated with any reported outcomes. Projects are not subject to IRB
review when a CSUSM employee consults on research but does not receive or possess
identifiable or private information about the persons participating in the study.

4. Foreign Country

Research conducted in a foreign country by or under the direction of an investigator
affiliated with CSUSM must be approved by the IRB and adhere to the university,
federal, and state guidelines.

5. Pilot Studies

Pilot studies that meet the definition of research that involves human subjects must
receive IRB review and approval prior to initiation. Pilot or feasibility studies may
include as little as one person must adhere to the same federal, state, and institutional
requirements to protect human subjects in research regardless of the number of subjects
involved.

6. Classroom Assignments & Student Projects

When classroom assignments and student projects are for the purposes of training and not
for published research or generalized knowledge, IRB may not be necessary. The course
instructor is responsible for including information about the ethical research practices and
providing direct supervision of each project. Projects conducted for this purpose should
not exceed minimal risk, target special populations, and/or include sensitive subject
matter.

a. If a classroom project is presented at a conference, it must clearly indicate that it is a
classroom project.

b. If the goal is publication and additional data will be gathered beyond the classroom
project/time period, the student must file an appropriate IRB application.

VIII. INFORMED CONSENT

Regardless of research category, as presented above, every investigator involving a
human being as a subject in research covered by this policy must obtain the legally
effective informed consent of the subject or the subject's legally authorized
representative. Exceptions to informed consent are when investigators apply for informed consent waivers or this requirement is modified by the IRB on a case-by-case basis.

A. General Requirements for Informed Consent

An investigator shall seek consent only under circumstances that:

1. Provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

2. Provide information given to the subject or the representative at a language level understandable to the subject or the representative and/or provide appropriate native language translation, should the subjects be non-English speakers and/or prefer to communicate in non-English language or dialect.

3. May not include any exculpatory language whether written or oral through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

B. Basic elements of informed consent (CFR 46.116)

Except when waived or modified by the IRB, informed consent must provide the following information to each subject:

1. A statement that the study involves research, an 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;

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

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

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

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

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

8. 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.

C. Additional elements of informed consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

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

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

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

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

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

7. If involving voice recordings or images, subject should be informed about how the voice recording or images may be used within the consent document. If the investigator would like permission to present the recordings for the purpose other
than the specific research for which the subject is consenting, an addendum to the consent is used to obtain this permission.

D. Modification or Waiver of Informed Consent

1. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

   a. 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.

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

2. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that all conditions below are satisfied:

   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; and,

   d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

E. Documentation of Informed Consent

1. Except when waived or modified, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. The consent form may be either of the following:
HUMAN SUBJECTS PROTECTION IN RESEARCH

Effective Date: 8/4/2008

a. A written consent document that embodies the elements of informed consent required by CFR 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed;

OR

b. A short form written consent document stating that the elements of informed consent required by CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

2. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

b. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

IX. ADDITIONAL PROTECTIONS FOR RESEARCH SUBJECTS

A. Pregnant women, human fetuses and neonates involved in research

All researchers using this population must comply with the additional protections for this population specified in 45 CFR 46 Subpart B (66FR56788, Nov. 13, 2001) unless otherwise noted.

B. Biomedical and behavioral research involving prisoners as subjects
All researchers using this population must comply with the additional protections for this population as specified in 45 CFR 46 Subpart C. (43 FR 53655, Nov. 16, 1978) unless otherwise noted.

C. Additional protections for children involved as subject in research

This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services, as specified in 45 CFR 46.401 Subpart D (48 FR 9818, March 8, 1983) unless otherwise noted.

Unless exempt, this section clarifies and expands protections for children in research involving survey, interview procedures, or participant-observations. Note: This does not apply to exempt research -- when research involves observation of children's public behavior and/or when the investigator(s) do(es) not participate in the activities being observed.

1. IRB duties regarding research with children

In addition to other responsibilities assigned to IRB, the IRB shall review and approve research that satisfies the conditions of all applicable sections:

a. No Greater than Minimal Risk. The IRB will approve research in which no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as specified in Informed Consent (Section VII.). (CFR 46.404)

b. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. The IRB will approve research in which it finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that: (CFR 46.405)

   (i) The risk is justified by the anticipated benefit to the subjects;

   (ii) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

   (iii) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in the requirements for Informed Consent (Section VII).

   (i) The risk is justified by the anticipated benefit to the subjects;

   (ii) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

   (iii) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in the requirements for Informed Consent (Section VII).

c. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. The IRB will approve research in which it finds that more than
minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that: (CFR 46.406)

(i) The risk represents a minor increase over minimal risk;

(ii) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(iii) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(iv) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in the requirements for Informed Consent (Section VII).

2. Requirements for permission by parents or guardians and for assent by children.

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 the requirements for Informed Consent (Section VII).

b. In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by the requirements for Informed Consent, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is to be deemed sufficient for research to be conducted under Section VII.C.1.a or VII.C.1.b above. Where research is covered by VII.C.1.c and permission is to be obtained from parents, both parents must give their permission unless one parent is
deceased, unknown, legally incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

c. In addition to the provisions for waiver contained in Waiver of Consent (Section VII. E), if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), it may waive the consent requirements in this section provided:

(i) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted and

(ii) that the waiver is not inconsistent with federal, state, or local law.

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

d. Permission by parents or guardians shall be documented in accordance with the requirements for Informed Consent (Section VII.A, B, and C).

e. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

3. Wards

Children who are wards of the state or any other agency, institution, or entity can be included in research approved under CFR 46.406 or CFR 46.407 only if such research is:

a. Related to their status as wards; or

b. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved under this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.