HUMAN SUBJECTS PROTECTION IN RESEARCH

Effective Date: 1/22/2019

Authority: Executive Order 890 Administration of Grants & Contracts in Support of Sponsored Programs; Code of Federal Regulations (CFR), Title 45, Public Welfare, Part 46, Protection of Human Subjects and related documents; Office of Human Research Protections.

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. This policy applies to human subjects research regardless of whether it is federally supported or not federally supported. 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.

Responsible Division: Academic Affairs

Karen S. Haynes, President — Approval Date: 1/18/2019

Graham Oberem, Provost & Vice President for Academic Affairs — Approval Date: 1/17/2019

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PREAMBLE

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.

PROCEDURE

I. DEFINITIONS (CFR 46.102)

A. General Definitions

1. ***Certification*** means the official notification by the institution to the supporting Federal department or agency component, 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.

2. ***Children*** refers persons who have not attained the legal age of consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person under 18 years old to be a child.

3. ***Clinical trial*** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

4. ***Department or agency head*** means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

5. ***Federal department or agency*** refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

6. A ***Federalwide Assurance (FWA)*** is an agreement made by an institution and the Department of Health and Human Services (HSS) that the institution will comply with HHS's Protection of Human Subject regulations at part 45 CFR 46.

7. ***Human subject*** means a living individual about whom an investigator (whether professional or student) is conducting research:
   a. obtains information or biospecimens through intervention or interaction with the individual, or analyzes the information or biospecimens; or

   b. obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

8. ***Intervention*** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

9. ***Interaction*** includes communication or interpersonal contact between investigator and subject.

10. ***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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

11. ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

12. ***An identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

13. ***Institution*** means any public or private entity, or department or agency (including federal, state, and other agencies).

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

15. ***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.

16. ***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. If there is no

applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

17. ***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.

18. The ***Office of Human Research Protection (OHRP)*** is a federal office that provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services. OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.

19. ***Public health authority*** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

20. ***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. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:
    a. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

    b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors,

patterns in disease, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

d. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security mission.

21. ***Written*****,** or ***in writing*****,** for purpose of this part, refers to writing on a tangible medium (e.g., paper) or in electronic format.

B. Local Definitions

1. ***California State University San Marcos Corporation (CSUSM Corporation)*** 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.

2. ***Code of Federal Regulations (CFR)*** is the guiding federal document for institutional policy and ethical standards related to research involving the use of human subjects.

3. ***University*** means California State University San Marcos (CSUSM).

II. RESPONSIBILITIES AND COMPLIANCE

A. Oversight

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 Dean of Graduate Studies and Research. It is the responsibility of the Office of Graduate Studies and Research to:

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

2. Maintain the CSUSM Federalwide Assurance for the Protection of Human Subjects (FWA) and comply with the requirements for documentation, reporting, and record maintenance.

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

4. 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. Work with the CSUSM Corporation and the IRB Chair to monitor changes in regulatory guidelines and to revise this policy accordingly.

B. IRB Chair

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. IRB Members

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 Office of Human Research Protection (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.

D. Notification of Policy

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. Ethical Practice Oversight

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. Faculty Supervisors

All research conducted by student investigators must have a faculty supervisor.

G. Supervising Faculty

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. Supervising faculty must maintain copies of training certificates for all involved research assistants.

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 (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects (CFR 46.101[f]).

3. This policy does not affect any foreign laws or regulations that may otherwise be applicable and that 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, if a Federal department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy (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. Members shall be appointed by the institutional official overseeing the IRB, i.e., the Dean of Graduate Studies and Research.

2. In addition, there shall be:
   a. One student representative,
   b. One representative of the CSUSM Corporation,
   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[c]) recommended by the Chair of the IRB and approved by majority vote of the committee.

3. The Dean of Graduate Studies and Research or designee, shall act as the Institutional Official and the Human Protections Administrator. The Dean of Graduate Studies and Research is the only non-voting member.

B. IRB Member Qualifications

The IRB shall be sufficiently qualified through the professional experience and expertise of its members, and the diversity of the members, including 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. Acceptability of Proposed Research

The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

D. Expertise with Specific Populations

If the IRB regularly reviews research that involves a vulnerable category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

E. Areas of Expertise

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[b]).

F. Conflicts of Interest

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.

G. Individuals with Specialized Expertise

The IRB may, using its 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 are not voting members of IRB.

IV. FUNCTIONS AND OPERATIONS OF THE IRB

A. IRB's Fulfillment of Policy Requirements

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

1. Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

2. Prepare and maintain a current list of the IRB members identified by name; earned degrees' representative capacity; indications of experiences such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant.

3. Establish and follow written procedures for:
   a. Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

   b. Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

   c. Ensuring prompt reporting to the IRB of proposed changes in a research activity, and ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

4. Establish and follow written procedures for ensuring prompt reporting to the Dean of Graduate Studies and Research; the department or agency head; and the Office of Human Research Protections, HHS, or any successor office, or equivalent office within the appropriate Federal department or agency of:
   a. Any unanticipated problems involving risks to subjects or others; or

   b. Any serious or continuing noncompliance with this policy; or

   c. Any serious or continuing noncompliance with the requirements or determinations of the IRB; or

   d. Any suspension or termination of IRB approval.

5. Except when an expedited review procedure is used, the IRB must review proposed research at convened meetings at which a 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. Approval of Research Activities
The IRB shall review and have authority to approve, require modifications to (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities for which limited IRB review is a condition of exemption (CFR 46.109 [a]).

C. Informed Consent
The IRB shall require that information given to subjects (or their legally authorized representative(s), when appropriate) as part of informed consent is in accordance with CFR 46.116. The IRB may require that information, in addition to that specifically mentioned in CFR 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects (CFR 46.109 [b]).

D. Documentation of Informed Consent
The IRB shall require documentation of informed consent if documentation of consent is not waived by IRB in accordance with CFR46.117 (CFR 46.109[c]).

E. Notice in Writing
The IRB shall 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. Continuing Review
The IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in CFR 46.109(f).

G. Exceptions to Continuing Review
Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

1. Research eligible for expedited review in accordance with CFR 46.110.

2. Research reviewed by the IRB in accordance with the limited IRB review described in CFR 46.102(d)(2)(iii), CFR 46.102(d)(3)(i)(C), or CFR 46.104(d)(7) or (8).

3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
   a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

   b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

H. Observation of Consent Process and Research
The IRB shall have authority to observe or have a third party observe the consent process and the research.

I. Expedited Review Procedure
(See Item XII. D.)

J. Administrative Review of Exempt Applications
The IRB shall have exempt applications reviewed administratively and approved by the IRB Chair, or designated voting members of the IRB committee.

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 that are consistent with sound research design and that 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 shall 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 shall 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. The IRB should be particularly cognizant of the special problems of

research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative(s), in accordance with, and to the extent required by CFR 46.116.

5. Informed consent will be appropriately documented or appropriately waived in accordance with CFR 46.117.

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

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

8. For purposes of conducting the limited IRB review required by CFR 45.104(d)(7), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:
   a. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of CFR 46.116(a)(1)-(4), (a)(6), and (d);

   b. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with CFR 46.117; and

   c. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

9. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

B. Review by Institution (CFR 46.112)

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

D. Cooperative Research (CFR 46.114)

1. Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

2. Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research unless more than a single IRB review is required by law or a Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

3. For research that is not supported or conducted by a Federal department or agency, the lead investigator should select the reviewing IRB by considering the history and experience of the IRB, as well as the IRB's capacity to serve as the IRB of record for the particular protocol. The selected IRB must be registered with OHRP and must have the expertise necessary to review the proposed research.

4. The following is not subject to this provision:
   a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) or

   b. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of the single IRB is not appropriate for the particular context.

5. For research not subject to a single IRB review, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another IRB, or make similar arrangements for avoiding duplication of effort.

VI. IRB RECORDS

A. Documentation of Activities

An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

2. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

3. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review.

4. Copies of all correspondence between the IRB and the investigators.

5. A list of IRB members in the same detail described in CFR 46.108(a)(2).

6. Written procedures for the IRB in the same detail described in CFR 46.108(a)(3) and (4).

7. Statements of significant new findings provided to subjects, as required by CFR 46.117(c)(5).

8. The rationale for an expedited reviewer's determination under CFR 46.110(b)(1)(i) that research appearing on the expedited review list is more than minimal risk.

B. Records Retention

The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records electronically or in printed form. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

VII. INFORMED CONSENT

A. General Requirements

General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements found in paragraphs (b) through (d) of this section. Broad consent may be obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information or identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

1. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

3. The information that is given to the subject or the legally authorized representative must be in language understandable to the subject or the legally authorized representative.

4. The prospective subject or legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

5. Except for broad consent obtained in accordance with paragraph (d) of this section:
   a. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

   b. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legal authorized representative's understanding of the reasons what one might or might not want to participate.

6. No informed consent may include any exculpatory language through which the subject or the legally authorized 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, or its agents from liability for negligence.

B. Basic Elements of Informed Consent (CFR 46.116) (b)

Except when broad consent has been obtained, or consent has been waived or modified by the IRB, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

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;

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; and

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
   a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens that, after such removal, the information of biospecimens could be used for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

C. Additional Elements of Informed Consent

Except when broad consent has been obtained, or consent has been waived or modified by the IRB, one or more of the following elements of information, when appropriate, 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) that are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative'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 that 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. A statement that the subject's biospecimens (event if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with intent to generate the genome or exome sequence of that specimen).

D. Biospecimens

Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Broad consent for the storage, maintenance and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or

nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

1. The information required in (B)(2), (B)(3), (B)(5), and (B)(8) and, when appropriate, (C)(7) and (C)(9) of this section;

2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

5. Unless the subject or legally authorized representative will be provided with details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

6. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

7. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

E. Waiver/Alteration of Consent

1. **Waiver:** An IRB may waive the requirement to obtain informed consent for research under paragraphs (A) through (C) of this section, provided the IRB satisfies the requirements of paragraph (E)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable

private information or identifiable biospecimens in accordance with the requirements at paragraph (D) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

2. **Alteration**: An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (B) and (C) of this section provided the IRB satisfies the requirements of paragraph (E)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (A) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (D) of this section.

3. **Requirements for Waiver and Alteration of Consent in Research Involving Public Benefit and Service Programs**:
In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:
    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.

4. **General Waiver or Alteration of Consent**
In order for the IRB to waive or alter consent as described in this subsection, the IRB must find and document that:
    1) The research involves no more than minimal risk to the subjects;
    2) The research could not practicably be carried out without the requested waiver or alteration;
    3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

4) The waiver or alteration will not adversely affect the rights or welfare of the subjects; and

5) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

F. Screening, Recruiting, or Determining Eligibility

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

G. Posting of Clinical Trial Consent Form

1. For each clinical trial conducted or supported by a Federal department or agency, one IRB approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

2. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g., confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

3. The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

H. Preemption

The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

I. Emergency Medical Care

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 (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

VIII. DOCUMENTATION OF INFORMED CONSENT

A. IRB Informed Consent Form

1. Except as provided in paragraph (B) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

2. Except as provided in paragraph (B) of this section, the informed consent form may be either of the following:
   a. A written informed consent form that meets the requirements of CFR 46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

   b. A short form written informed consent form 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, and that the key information required by CFR 45.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized 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 subject's legally authorized representative, in addition to a copy of the short form.

B. Waiver of Documentation of Informed Consent

1. An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:
   a. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

   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; or

c. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

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

IX. APPLICATIONS AND PROPOSALS LACKING DEFINITE PLANS FOR INVOLVMENT OF HUMAN SUBJECTS

Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or 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. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under CFR 46.101(i) or exempted under CFR 46.ll.104, 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, by the institution, to the Federal department or agency component supporting the research.

X. RESEARCH UNDERTAKEN WITHOUT THE INTENTION OF INVOLVING HUMAN SUBJECTS

Except for research waived under CFR 46.101(i) or exempted under CFR 46.104, 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, a certification submitted by the institution to the Federal department or agency component supporting the research, and final approval given to the proposed change by the Federal department or agency component.

XI. 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 Coursework, Exempt, or Expedited Review, 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.

XII. 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, children, individuals with impaired decisions-making capacity, and educationally or economically disadvantages persons.

A. Exempt Review (CFR 46.104)
Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories in paragraph (C) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section as specified in each category. A "Request for Exempt Status" must be submitted for review and approval by members of the IRB.

B. Use of Exemption Category
Use of the exemption category for research subject to the requirements of subparts B, C, and D, is as follows:

1. Subpart B. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

2. Subpart C. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

3. Subpart D. The exemptions at paragraphs (C)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (C)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (C)(2)(iii) of this section may not be applied to research subject to subpart D.

C. Human Subjects Exemption Categories

Except as described in paragraph (A) of this section, the following categories of human subjects research are exempt from this policy:

1. Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
   a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

   b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

   c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by CFR 46.111(A)(7).

3. Benign behavioral interventions.
   a. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to

the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by CFR 46.111(A)(7).

b. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

c. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

a. The identifiable private information or identifiable biospecimens are publicly available;

b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under

45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or

d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

6. Taste and food quality evaluation and consumer acceptance studies:
   a. If wholesome foods without additives are consumed, or

   b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by CFR 46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
   a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with CFR 46.116(a)(1) through (4), (a)(6), and (d);

   b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with CFR 46.117;

   c. An IRB conducts a limited IRB review and makes the determination required by CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (D)(8)(a) of this section; and

   d. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

D. Expedited Review (CFR 46.110)

1. The Secretary of HHS has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

2. An IRB may use the expedited review procedure to review the following:
   a. Some or all of the research appearing on the list described in paragraph (1) of this section, unless the reviewer determines that the study involves more than minimal risk;

   b Minor changes in previously approved research during the period for which approval is authorized; or

   c Research for which limited IRB review is a condition of exemption under CFR 46.104(d)(2), CFR 46.104(d)(3)(i)(C), and CFR 46.104(d)(7) or (8).

3. Under an expedited review procedure, the review may be 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 in accordance with the non-expedited procedure set forth in CFR 46.108(b).

4. The IRB shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure.

E. 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 that a full review is required:

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 or individuals with impaired decision-making capacity.

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.

XIII. 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 Subjects 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

2. 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).

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

3. 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 an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further 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.

4. Wards
   a. 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:
      i. Related to their status as wards; or

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

   b. 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.