

California State University, Los Angeles

Institutional Review Board -
Human Subjects

Regulations and Procedures¹

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¹ The procedures in this document are drafted to implement the policy stated in the CSULA *Faculty Handbook* and the regulations stated in the 45 *Code of Federal Regulations* 46.

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IRB Regulations and Procedures*

1.0 Background and General Information

1.1 Institutional Responsibility

Institutions receiving U.S. Department of Health and Human Services (DHHS) funds to conduct research with human participants must assume responsibility for the protection of the rights and welfare of human subjects in compliance with federal regulations. Each institution is required to document this information within a Federalwide Assurance issued by the U.S. Department of Health and Human Services Office of Human Research Protections. Federalwide assurances state the requirements and procedures for human subjects protections to ensure that all research conducted within its jurisdiction complies with the Code of Federal Regulations pertaining to human subjects (DHHS Policy - 45 *CFR* 46). These regulations require institutions to establish an Institutional Review Board (IRB) and an institutional mechanism to review for approval all research protocols involving the use of human subjects. At Cal State LA, the IRB is known as the Institutional Review Board—Human Subjects.

1.2 Institutional Support

Administrative support for the Cal State LA Institutional Review Board—Human Subjects (IRB) is provided through the Office of Research and Sponsored Programs, as designated by the Provost and Vice President for Academic Affairs, with policies established by the Academic Senate. This office is also responsible for establishing and maintaining a program in support of ethical and responsible human subjects research conducted under the auspices of Cal State LA. The Dean of Graduate Studies and Research serves as the Institutional Official, the Director of Research Administration serves as the Human Protections Administrator, and the IRB Coordinator provides administrative review and support.

1.3 IRB Responsibility

The IRB implements a review process established within the *Code of Federal Regulations* to ensure that human subjects 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. The IRB also provides assistance to the investigator in complying with federal and state regulations and institutional standards for human subjects research. The IRB is guided by the ethical principles as set forth in the Declaration of Helsinki and *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, also known as the Belmont Report.

1.4 IRB and Institutional Authority

The IRB may approve research reviewed or may require that modifications to the protocol be made to secure approval to conduct the research. The IRB may also deny approval of research. Decisions made by the IRB are communicated in writing to the investigator (45 *CFR* 46.109). The IRB may also suspend or terminate approval of research that is not conducted in accordance

with the approved protocol or that has been associated with unexpected serious harm to subjects (45 *CFR* 46.113). Actions taken by the IRB to suspend or terminate approval will be documented in writing, including a statement of the reasons for the IRB's action, and reported to the investigator, institutional officials, and, for federally funded research, the appropriate department or agency head. Serious and continuing noncompliance will also be reported to the Office for Human Research Protections (OHRP).

Research that is approved by the IRB may be subject to further review by the officials of the institution. Authorized institutional officials may approve or disapprove research planned by an employee, student, or agent of the University. However, the institutional officials may not approve research involving human subjects that has not been approved by the IRB (45 *CFR* 46.112). The University may suspend or terminate any human subject research of any researcher who has not met the federal requirements or institutional policies or who has failed to secure IRB review and approval. ***Any researcher who has not obtained IRB approval to conduct funded human subject research may not have the University's legal protection and may jeopardize all research conducted under the aegis of the institution.***

1.5 IRB Membership

1.5.1 IRB Composition and Selection

The composition of the IRB, consistent with federal requirements (45 *CFR* 46.107), is stated in the *Faculty Handbook* as follows:

- eight faculty members from at least two different colleges, having expertise in medical, physical, psychological, social, or legal risks, nominated and elected for staggered four-year terms by the Nominations Committee of the Academic Senate;
- the Medical Chief of Staff or designee;
- one public member and one alternate public member who are not otherwise affiliated with the University and who are not part of the immediate family of a person affiliated with the University, appointed by the President and subject to approval by the Nominations Committee;
- one upper division graduate or postbaccalaureate student who is knowledgeable regarding medical, physical, psychological, social, or legal risks, selected annually by the Board of Directors of the Associated Students, Inc.; and
- the Director of Research Administration, who serves *ex officio* as executive secretary, nonvoting, as designee of the Provost and Vice President of Academic Affairs.

The Director of Risk Management and Environmental Health and Safety attends as a guest.

At least three of the eight faculty members are practicing scientists experienced in research involving human subjects. The primary academic background of at least three other faculty members is in a nonscientific area. The IRB includes a diversity of members, representing a variety of disciplines representative of the research reviewed. The Human Protections Administrator and the IRB Coordinator will confirm that IRB membership is in compliance with regulations (46.107). Re-election or appointment may occur provided that the member

demonstrates an interest in research ethics, knowledge of regulations and ethical standards in ascertaining the acceptability of proposed research, and has the time to devote to associated responsibilities.

1.5.2 Alternate or Replacement Member

An alternate member may be appointed to the Committee using the same appointment method for one or more quarters to serve in the absence of a member upon the member's request. Due to the diversity in an individual's academic and/or professional training as well as experience, an alternate member is selected to represent an absent member (if needed) using the following criteria: scientist, nonscientist, community member, prisoner representative, or student (45 *CFR* 46.107).

1.6 IRB Member Responsibilities

1.6.1 Member Training

IRB members participate in initial and continuing education by reviewing relevant materials on issues, regulations, and guidance concerning human subjects protections (45 *CFR* 46.107). Successful completion of the IRB tutorial assessment is a mechanism for the Cal State LA research community, (<http://ohrp.osophs.dhhs.gov/polasur.htm#REG> including IRB members), to demonstrate a basic understanding of both federal and Cal State LA-specific ethical principles and regulatory compliance practices. In addition to annual completion of the IRB tutorial, IRB members are provided with copies of the *Institutional Review Board Guidebook* (http://www.hhs.gov/ohrp/irb/irb_guidebook.htm); *Code of Federal Regulations* (45 *CFR* 46) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>); and the Belmont Report, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>). Further training is provided by the IRB Coordinator on an ongoing basis through distribution of relevant newsletters and articles, as well as through discussion of relevant regulation updates and special topics.

1.6.2 Reviewer Expertise (Research Involving Children, Prisoners, etc.)

The IRB membership includes those familiar with the type of research routinely conducted primarily in the social and behavioral sciences, but also in the health and biological sciences. One member serves as the prisoner representative, in accordance with 45 *CFR* 46.107, to provide expertise in review of research involving prisoners, institutionalized youths, and children who are wards of the court. Individuals invited to comment due to their expertise may not vote. The IRB recognizes that additional expertise may be necessary when reviewing a protocol, and may request consultation from an individual with competence in a specific area when issues relevant to a protocol require expertise above or beyond that available on the IRB.

1.6.3 Review Process

For review by the convened committee, all members will receive the entire application packet, including the protocol, consent documents, recruitment materials, and other supporting documents (study instruments, letters of permission, etc.). The Chair or other designated IRB member and

the IRB Coordinator will also receive a copy of the grant proposal, if applicable. For final expedited review, the Chair or the Vice Chair will receive the entire initial review application packet, as noted above.

1.7 Quorum and Voting Requirements (45 CFR 46.107 and 46.108)

To convene a meeting of the IRB, a majority of the voting members of the IRB must be present, including at least one member whose primary academic background is in a nonscientific area. If the quorum fails during the meeting (early departures, loss of nonscientist, conflict of interest), the meeting will be terminated until the quorum can be restored. No action may be taken without a quorum present. *Robert's Rules of Order* is followed.

Individuals designated as nonvoting members may contribute to discussion; however, they may not propose a motion or vote on a motion. In order for a motion to pass, it must receive the approval of a majority of voting members present at the meeting.

1.8 IRB Member Conflict of Interest

Regulations stipulate that an IRB member may not participate in the initial or continuing review of a project in which the member has a conflicting interest, except in response to information requested by the committee (45 CFR 46.107e).

2.0 Human Subjects Research and IRB Review

The IRB reviews research when procedures are proposed to obtain information about a living individual through the use of a survey, interview, observation, or experimentation, or the analysis of human tissues, records, samples, or other data previously collected from human subjects. All research involving human subjects must be reviewed and approved by the IRB in advance of study initiation. The IRB reviews both funded and unfunded research projects, whether they are conducted by faculty, staff, or students of the University, or by researchers not affiliated with the University but whose research involves campus personnel.

An IRB review is required when a study meets the criteria as defined by the federal regulations as human subjects research.

2.1 Definitions

In determining whether or not a project requires review by the IRB, the first step is to determine if the project is research and to then identify whether the people involved are also human subjects. The IRB only reviews activities that involve the participation of human subjects in research. See the following sections for definitions.

2.1.1 Research

The Department of Health and Human Services (DHHS) *Code of Federal Regulations* (45 CFR 46.102d) has defined research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." As

described in the Belmont Report, "...the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).

45 *CFR* 46.102f specifies that engagement in research occurs when an investigator “obtains data through intervention or interaction with an individual or identifiable private information” (see 2.1.2 above). “*Intervention* includes both physical procedures by which data are gathered (for example, 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. *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.”

2.1.2 Human Subject

A human subject is defined as “a living individual *about whom* an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction or (2) identifiable private information.” (45 *CFR* 46.102f)

2.1.3 Generalizable Knowledge

The IRB considers generalizable knowledge to include the dissemination of research findings beyond the boundaries of the institution, e.g., publication (including thesis or dissertation) or presentation or use outside the specific instructional setting.

2.2 IRB Review

IRB review is required when any University or its auxiliary organizations employee, student, or agent, or anyone utilizing any property or facility of this institution, is *engaged* in human subjects research (<http://hhs.gov/ohrp/humansubjects/assurance/engage.htm>). Projects conducted by or under the direction of any employee, student, or agent of Cal State LA in connection with his or her institutional responsibilities, and projects that utilize any property or facility of this institution, whether funded or not funded, are subject to the federal regulations governing such research (see 45 *CFR* 46 and The Belmont Report), and to the policies and procedures outlined in Cal State LA’s Assurance of Compliance. IRB review and approval must occur in advance of study initiation.

2.3 Special Considerations

- Studies in which the duties of the principal investigator are formally contracted to a non-institutional performance site must obtain approval from an IRB designated for that institution in addition to review requirements imposed by the Cal State LA IRB.

- When a researcher who is an employee of the institution is hired on his/her own time, does not utilize the institution's resources, and will not reference the institution in documents or publications associated with any reported outcomes, Cal State L.A. IRB review is not required, as the study is outside of the employment scope.
- Unless there is a formal agreement established between Cal State LA and other institutions, the Cal State LA IRB will not accept without further review projects approved by other institutions. Where there is a formal agreement, the Cal State LA IRB will accept without further review projects approved by those institutions, unless human subjects are to be recruited or will undergo research procedures at Cal State LA, or if Cal State LA is receiving any funding for the project. In the latter case, the Cal State LA IRB will require an application.
- In doing research in foreign countries, IRB approval must be obtained from a comparable approval mechanism to that of the IRB in addition to review requirements imposed by the Cal State LA IRB. Where there is no comparable approval mechanism, approval must be obtained in the form of a letter from an authorized official at each site, on official letterhead, giving permission for the research to be conducted at that location.
- Pilot or feasibility studies that meet the definition of research involving human subjects must receive IRB review and approval prior to initiation.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens may be reviewed by the IRB or may qualify for a waiver.
- Persons not affiliated with the institution requiring the use of institutional facilities, students, and/or employees in their research must obtain a campus sponsor prior to submitting an application to the IRB. An affiliated employee (faculty or administrator) with sufficient expertise in the research area may act as the campus sponsor.
- Course assignments are not considered to be research as defined within the federal regulations and are not subject to IRB review. Projects conducted for this purpose should not exceed minimal risk, target special populations, or include sensitive subject matter. If the assignment results in findings that the student may want to present or publish, it is recommended that the study be replicated and conducted under an IRB-approved protocol.

3.0 Review Process and Procedures

3.1 Intake and Prereview Process

The IRB Coordinator is responsible for an initial intake review upon submission of all protocol documents to the Committee. The IRB Coordinator will reject, without further review, any application that is incomplete, and will not do a more thorough prereview of the application until all intake requirements have been met.

The IRB Coordinator will not forward any application for expedited or convened committee review until all prereview requirements have been met. For applications that qualify for exemption, this will be the only review process.

3.2 Review Requirements

The IRB will review research involving human subjects to assure that the protocol meets with federal, state, and institutional regulations.

There are three different procedures that are used to review an application: Exempt, Expedited, and Convened (Full) Committee. The appropriate review procedure is determined by federal regulations and applied analysis based on how human subjects are involved in the research. The type of review is based on risk associated with participation in the research, the study intervention/interaction, and how informed consent is obtained and documented. A research protocol, informed consent statement, and additional supporting documents are required for all research projects submitted for review.

The IRB reviews the study protocol to determine study benefit and to assess risk and risk management procedures. Part of the process of risk/benefit analysis includes reviewing what has been done in the past and what should be done in the future in order to gain a better understanding of the phenomenon under study. The IRB may review a summary of the literature and other background information in order to justify approval of the proposed study.

The IRB is required to evaluate whether subject selection procedures are fair to ensure that the burdens of research participation are distributed equitably across groups of people. In addition, the IRB must consider recruitment procedures to ensure that a broad cross-section of research subjects is included in the research and to evaluate the procedures that will be established to protect subject privacy during the recruitment phase.

There are specific federal regulations (45 *CFR* 46 Subparts B-D) that apply to conducting research with vulnerable populations. These regulations assure that the risks associated with participation are minimal or that the research is of direct benefit to the subjects. Additional safeguards for all subjects that are likely to be vulnerable to coercion or undue influence must be included in the study to protect the rights and welfare of these subjects.

3.3 Administrative Review

Research that is considered minimal risk and that meets federal criteria for an exempt or expedited review (e.g., use of existing data; some survey or interview procedures) is eligible for review through administrative procedures (45 *CFR* 46.101 & 45 *CFR* 46.110). All nonexempt research will be reviewed through IRB expedited review or by the convened committee.

3.3.1 Exempt Review

The IRB Coordinator may review research that qualifies for an exempt review using the criteria listed below. An investigator may not determine whether his or her own research is exempt, according to OHRP guidance memoranda.

The following types of research qualify for an exempt review (45 *CFR* 46.101):

(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, unless:

- (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2), if

- (i) the human subjects are elected or appointed public officials or candidates for public office; or
- (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) 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.

This form of research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens may qualify for a waiver. In order to qualify for a waiver, the archival or reanalyzed data sources must not reveal information that may have implications for the privacy, reputation, employability, or insurability of classes or individuals. Applications qualifying for a waiver will be filed in the Office of Research and Sponsored Programs; no formal review will be conducted. However, applications are subject to periodic IRB audit to assure compliance. Research that does not qualify for a waiver may qualify for exemption, and can be verified through an administrative review of the standard application form (45 *CFR* 46.101).

(5) 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:

- (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,
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies,
- (i) if wholesome foods without additives are consumed or
 - (ii) 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.

3.3.2 Expedited Review

The IRB Chair or the Vice Chair may review research that qualifies for an expedited review using the criteria listed below. When conducting an expedited review, the IRB Chair or the Vice Chair has the authority to act on behalf of the IRB with the exception of disapproving the research.

The following types of research qualify for an expedited review:

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

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

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

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) 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.

(2) 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.

(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) 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.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

(7) Research 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. (*Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.*)

(8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) 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.

3.4 Convened (Full) Committee Review

If the research is not eligible for an exempt or expedited review the protocol must be reviewed by the convened IRB membership at its meeting.

The committee will vote on a motion to either: 1) approve the protocol as it stands, 2) request revisions to the protocol to secure final approval, 3) request that additional information be provided prior to further review by the convened committee, or 4) deny approval for the protocol.

3.5 Approval Criteria

For approval of a research protocol, the following federal requirements must be satisfied (45 CFR 46.111):

- Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.

- 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.
- Selection of subjects is equitable.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, the cognitively impaired, or economically or educationally disadvantaged), additional safeguards have been included in the study to protect the rights and welfare of these subjects.

3.6 Funded Research

The investigator must append the narrative section of the grant proposal to his or her IRB application (45 *CFR* 46.103f). In addition, the title of the IRB application must be consistent with the grant that the protocol represents.

3.7 Preliminary Approval

If the research lacks definite plans for involvement of human subjects, a Preliminary Approval may be appropriate (45 *CFR* 46.118). This process allows for the investigator to disclose plans to conduct research and to demonstrate understanding that human involvement in the research cannot occur until the IRB approval is secured. This occurs when the research plan has not been completely developed or material development will occur prior to any involvement with subjects.

45 *CFR* 46.118: Certain types of applications for grants, cooperative agreements, or contracts are submitted to 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 or prior animal studies. These applications need not be reviewed by an IRB before an award may be made. 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 department or agency.

3.8 Review Decisions

If the research is approved, an email and hard copy memo, stating the approval date and terms of approval, will be sent to the investigator. If the research is denied, the investigator may not conduct the research. The IRB will provide the investigator with the reason for its decision. The investigator may resubmit a protocol to the IRB for review if the reasons given for disapproval can be corrected and addressed. IRB approval is valid for up to one year from the date of initial review (45 *CFR* 46.109). To initiate the appeal of an IRB decision, the investigator must submit a statement to the IRB noting areas of contention. If the issue is not resolved through the IRB, the appeal will be forwarded to the Dean of Graduate Studies and Research, who serves as the Institutional Official.

Modifications may be required to secure approval if there are correctable problems found in the protocol. The IRB determines, upon review, whether the investigator's response to stipulations will require subsequent review by the convened committee or can be reviewed administratively by the IRB Coordinator, Human Protections Administrator, IRB Chair, or designated IRB members. The IRB may postpone review and approval if a determination is made that there is insufficient information provided by the researcher.

Protocols that are verified as exempt do not need further review so long as no changes are made to the protocol.

4.0 Informed Consent

4.1 Consent Purpose

The Office for Human Research Protections (OHRP) states that "informed consent is one of the primary requirements underpinning research with human subjects; it reflects the basic principle of respect for persons."

4.2 Consent Process and Procedures

The following procedures should occur during the informed consent process (45 *CFR* 46.116):

- The prospective subject is given adequate information to make an informed decision about participating in the proposed study.
- The nature and expectations of the research including risks and benefits is explained to the subject.
- The study is presented in a language that is clear and understandable.
- The subject receives answers to questions he or she may have about the study.
- The study is explained in an appropriate setting and with enough time conducive to good decision-making.
- The prospective subject comprehends the information and can make a choice about whether he or she wants to participate.

- The prospective subject understands that he or she retains the right to refuse or withdraw from the study at any time without penalty.
- The prospective subject and/or the parent or guardian is given copies of the approved consent form(s).
- In addition, the investigator must retain the signed copies of the consent document for a minimum of three years following completion of the study.

4.3 Alternative Consent Procedures (45 CFR 46.116 (6c))

The IRB may approve a consent procedure that does not include or changes the basic consent requirements or even waive the requirement to obtain informed consent when the following applies and can be documented:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

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

The IRB may also approve a consent procedure that does not include or alters the basic consent requirements or even waive the requirement to obtain informed consent when the following applies and can be documented:

- (1) the research involves no more than minimal risk to the subjects,
- (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects,
- (3) the research could not practicably be carried out without the waiver or alteration, and
- (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Note: The regulations referenced do not preempt any applicable federal, state, or local laws that require additional information to be disclosed in order for informed consent to be legally effective.

4.4 Documentation of Informed Consent (45 CFR 46.117)

In most cases, informed consent is 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.

Unless the IRB has authorized revisions to the consent procedure, the consent form must include all elements identified within the IRB-approved consent template. The IRB-approved consent form may be read to the subject or to the subject's legally authorized representative in addition to

allowing the potential subject an opportunity to review the consent document and ask questions before signing the consent document.

4.5 Waiving Requirement to Document Consent (45 CFR 46.117(c))

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

(1) 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. If this is the case, the investigator will ask the subject whether he or she wants to sign the document that links him or her to the research. The subject's wishes for documentation will dictate whether or not a signed consent form is needed.

(2) 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.

5.0 Studies Involving Special Populations or Vulnerable Subjects

Special populations or vulnerable subjects include children, pregnant women, prisoners, and physically or cognitively challenged, economic or socially disadvantaged, subordinate individuals (e.g., students and employees), and fetuses. Additional safeguards for all subjects that are likely to be vulnerable to coercion or undue influence must be included in the study to protect the rights and welfare of these subjects (45 CFR 46.111(7)(b)).

The degree to which these potential subjects are vulnerable is directly related to the degree to which these individuals are capable of volunteering or providing informed consent to research participation. There are specific federal regulations (45 CFR 46 Subparts B - D) that apply to conducting research with vulnerable populations. These regulations assure that the risks associated with participation are minimal or that the research is of direct benefit to the subjects. Special considerations will be made by the IRB in reviewing protocols that include vulnerable subjects.

5.1 Children

The *Code of Federal Regulations* (45 CFR 46.401 Subpart D - <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#subpartd>) describes additional protections for children involved as subjects in research. A child is defined by the State of California as a person who is under the age of 18 years and is not legally emancipated (link to state law on emancipation; <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=fam&group=06001-07000&file=7000-7002>).

The IRB may only approve research involving children when all conditions of this subpart are satisfied as follows:

- The research does not involve more than minimal risk (i.e. does not expose the child to greater risk than encountered in daily life).
- The research involves greater than minimal risk; however, the individual subject may receive direct benefit from participating in the research.
- The research involves greater than minimal risk and no prospect of direct benefit to the participant; however, the results of the research will contribute to generalizable knowledge about the subject's disorder or condition.
- The research, while otherwise not approvable, presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

5.1.1 Involving Children in Research at School

School children can be involved in research when the data collected will be used to assess classroom instructional strategies/techniques, curriculum development, or classroom management techniques. Information should be included on what is part of the usual classroom routine and what is different from the usual routine. Discussion should include whether class time is used or if children are participating outside of structured class time (address what non-participating students will be doing while the study is conducted, including whether they will have the opportunity to receive the same benefits at another time; supervision of non-participants; and procedures used to pull out children/subjects during class time).

5.2 Pregnant Women

The *Code of Federal Regulations* (45 CFR 46.401 Subpart B - <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#subpartb>) provides additional safeguards for research that involves fetuses, pregnant women, and human in vitro fertilization. The IRB must determine that all aspects of the research comply with this subpart, and must give special consideration to subject selection, monitoring, and oversight of informed consent, and monitoring the research as needed. Pregnant women or fetuses may be involved in research if all of the following conditions are met:

- (a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
- (b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.
- (c) Any risk is the least possible for achieving the objectives of the research.
- (d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman

nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part.

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

(g) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part.

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

5.3 Cognitively Impaired (45 CFR 46.111(b))

When recruiting participants who are cognitively impaired, the investigator must evaluate whether the potential subject is capable of making an informed choice to participate in the research. The process used by the investigator to determine participant autonomy must be described in the protocol. If the individual is deemed competent to make an informed choice, it may be necessary to include additional procedures during the consent process to ensure that the prospective subject understands the information presented about the study. The investigator may consider including questions at the end of each section of the consent document to use in assessing participant comprehension of the consent content. This mechanism allows for the investigator to clarify the participant's understanding of specific aspects of the study as the consent process. If the individual is not legally able to consent for him/herself, the person who is legally authorized to serve as the individual's advocate and caretaker is responsible for determining whether the proposed study is appropriate.

5.4 Prisoners (45 CFR 46.401 Subpart C)

The *Code of Federal Regulations* 45 CFR 46.401 Subpart C (<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#subpartc>) allows the IRB to review and approve research that includes prisoners when the following conditions are met: The study does not place the subject at more than minimal risk and the investigation pertains to possible causes, effects, and processes of incarceration and of criminal behavior, or the investigation pertains to prisons as institutional structures or of prisoners as incarcerated individuals, or the investigation pertains to conditions that affect prisoners as a class of people

(e.g., research on disease that is more prevalent in prisoners than other groups; research on social and psychological problems of prisoners such as alcoholism, drug addiction, and sexual assaults), or the study has the likelihood of improving the health or well-being of the prisoner.

5.5 Women and Minorities

Federal guidelines require that NIH-funded studies incorporate a research design that is sufficient to elicit information about individuals of both sexes/genders and diverse racial and ethnic groups in order to examine differential effects of research procedures on such groups. For more information on this topic, please go to:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

5.6 College Students

The IRB tries to estimate the degree of situational coercion and assist investigators in reducing the pressure that a student may experience when recruited to participate in research. The IRB encourages investigators to follow recruitment procedures intended to create the opportunity for students to participate in research while reducing the possibility of unintended coercion. If research participation is a course requirement, offer an equitable alternative to participation in a study as a method of obtaining course credit (e.g., summarize a journal article, attend a research lecture, assist with data collection). The protocol needs to identify how voluntary participation will be ensured if the subjects under study are recruited by their professor. Recruitment procedures should allow for students to participate in the study without jeopardizing their grades or their relationship with their professor or the University.

5.7 Employees

The IRB must consider the potential for coercion or undue influence and breaches of confidentiality when employees are recruited as research subjects. Information should be included on how voluntary participation will be ensured if the subjects under study are recruited by their employer. Recruitment procedures should allow for employees to participate in the study without jeopardizing their job status, their pay, or their relationship with their supervisors.

6.0 Conducting Research after IRB Approval

6.1 Investigator Responsibility

Protecting the rights and welfare of the research subject is a shared responsibility of the IRB and the investigator. Ultimately, the investigator is responsible for the conduct of the study. This includes the application and monitoring of ethical practices, compliance with state/federal regulations and institutional practices, and supervision/training of research staff. Individuals conducting research under the auspices of the institution are required to comply with all federal, state, and institutional regulations and policies for the protection of human research subjects. Investigators will document their understanding of their responsibilities by signing the application form. Failure to conduct research in accordance with the IRB's requirements may result in suspension or termination of approval of the research.

6.2 Faculty Adviser's Responsibility when Supervising Student Research

Student-initiated research involving human subjects, whether dissertation, thesis, or other research projects, must be supervised by an authorized faculty member to ensure compliance with procedures and regulations relating to the protection of human subjects. The supervising faculty member is responsible for the following aspect of the student's involvement in research:

- Ensure that the student has reviewed and understands the federal regulations that govern research involving human subjects, the Belmont Report, and Cal State LA's Procedures prior to developing a study that involves human subjects.
- Meet with the student investigator to monitor the study progress.
- Be available to the student investigator to supervise and address problems should they arise.
- Oversee the prompt reporting of any unanticipated problems or significant or untoward adverse effects within five working days of occurrence.
- Arrange for an alternate faculty sponsor to assume these duties when unavailable (vacation or sabbatical).
- Monitor the research activity to ensure that the protocol approved by the IRB is followed.

By signing the application form, the faculty adviser will verify that he or she will comply with the stated responsibilities.

6.3 Campus Sponsor's Responsibility when Supervising Non-affiliated Research

Non-affiliated research involving human subjects must be supervised by an authorized faculty member or administrator to ensure compliance with procedures and regulations relating to the protection of human subjects. The campus sponsor is responsible for the following aspect of the non-affiliated researcher's involvement in research:

- Ensure that the researcher has reviewed and understands the federal regulations that govern research involving human subjects, the Belmont Report, and Cal State LA's Procedures prior to developing a study that involves human subjects.
- Be available to the investigator to supervise and address problems should they arise.
- Oversee the prompt reporting of any unanticipated problems or significant or untoward adverse effects within five working days of occurrence.
- Arrange for an alternate campus sponsor to assume these duties when unavailable (vacation or sabbatical).
- Monitor the research activity to ensure that the protocol approved by the IRB is followed.

By signing the application form, the campus sponsor will verify that he or she will comply with the stated responsibilities.

6.4 Modifications and New Findings

Any revision to previously approved research involving human subjects receive IRB approval in advance of implementation, except when necessary to eliminate apparent immediate hazards to the subject (45 *CFR* 46.103 (b)(4)(iii)). A modification is defined by the IRB as a change that does not alter the overall character or purpose of the original project. Minor changes that do not adversely alter the overall risk-benefit profile of the study may receive an expedited review. The convened committee reviews proposed changes that may affect the willingness of enrolled subjects to continue participation and/or increase the risk to research subjects.

A modification request requires completion of an application form with new signatures. Within the modification request, the researcher is asked to provide a complete description of and rationale for the proposed modification and to address the effects of the modification on risks, benefits, risk reduction, and informed consent. Any new findings in the literature that may influence the study procedures, risks, or benefits must also be reported to the IRB.

Changes to the consent document to inform subjects of new findings, changes in procedures, risks and benefits to study participation must also be approved by the IRB. Procedures used to inform and document consent of previously enrolled subjects affected by the modification should be addressed.

6.5 Reporting of Adverse Events

The investigator of an IRB-approved protocol must report any serious or unanticipated events involving risks to research subjects or others that are associated with the study procedures. Any undesirable experience associated with the research may be considered an adverse event. The event is considered serious and should be reported when the subject experiences recurring problems, unanticipated side effects, and/or death. Failure to report an adverse event to the IRB may result in temporary or permanent suspension of the protocol approval. Research associated with unexpected serious harm to subjects may also result in temporary or permanent suspension of the protocol approval.

If a subject is injured on campus during the course of the study, they are eligible for first aid services at the Student Health Center regardless of student status. For Cal State L.A. students, care for the injury may extend beyond first aid.

6.6 Continuing Review of Approved Protocols (45 *CFR* 46.109(c))

Research projects must be reviewed at least annually. The initial IRB approval expires one year following its award, unless otherwise stipulated by the IRB. Determination for more frequent review is based on the degree of risk associated with participation and/or the involvement of subjects that require additional protections as defined by the Department of Health and Human Services. Protocols that are verified as exempt do not need further review so long as no changes are made to the protocol.

A continuation of approval is needed if subject recruitment and/or data collection is continuing. To apply for continuation of approval, the investigator must complete a short form. Research that was initially reviewed by the convened committee will receive continuing review by the convened committee unless identified as not exceeding a minimal level of risk at the time of its initial review.

The continuation of approval request should include the following: a progress report, explaining briefly what the study is about, including the number of subjects intended for study; what has been accomplished since the last review, including, wherever possible, the number of subjects accrued; a summary of any significant adverse events or unexpected problems; a summary of protocol revisions approved by the IRB since the last review; research to be done during the subsequent review period; current literature that may influence the conduct of the study; an update of financial interests (if applicable); and any relevant attachments, e.g., updated survey instruments, current consent/assent forms/informational letters.

6.7 Site Monitoring

Continuing review may also involve a site visit by an IRB representative to the research facility. The goal of the site visit is to assess whether the protocol is being carried out as approved by the IRB. A secondary goal is to provide assistance to the investigator and key personnel, as needed, to increase understanding of the ethical principles associated with human subject protections and federal regulations. Specific areas targeted for review of the protocol include recruitment methods and materials, measures, eligibility criteria, compensation, informed consent procedures, IRB records, data management, and record keeping. Relevant study materials (e.g., correspondence, recruitment materials, subject files, measures, etc.) are made available for review during the site visit (as required by 45 *CFR* 46.109 (e)). The IRB may recommend a site visit for research studies that involve vulnerable populations, a longitudinal design, and/or procedures exceeding minimal risk. A site visit may also occur if a serious adverse event has occurred or a complaint has been registered.