

Procedures and Guidelines for Human Subjects Research

California Polytechnic State University, San Luis Obispo

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Introduction

The purpose of the Cal Poly *Procedures and Guidelines for Human Subjects Research* is to provide information to support investigators who must obtain approval from the Cal Poly [Institutional Review Board \(IRB\)](#), and to provide guidance on the Cal Poly [Policy for the Use of Human Subjects in Research](#). Copies of the *Procedures and Guidelines for Human Subjects Research* are available from the [Office of Research and Economic Development \(ORED\)](#). Other guidance not included in this document is available on the [ORED Human Subjects webpage](#).

When is Review Required?

Review by the Cal Poly IRB is required when a study meets the criteria as defined by the [Federal Regulations](#) as human subjects research and Cal Poly is engaged in the research as defined by the Federal Regulations and Cal Poly [Policy for the Use of Human Subjects in Research](#). This occurs when an agent, employee, or student of Cal Poly:

1. Receives an award through a grant, contract, or cooperative agreement directly for research with human subjects, even where all activities involving human subjects are carried out by employees or agents of another institution;
2. Intervenes for research purposes with any human subjects by performing invasive or noninvasive procedures, such as invasive or noninvasive procedures include drawing blood, collecting buccal mucosa cells using a cotton swab, administering individual or group counseling or psychotherapy, administering drugs or other treatments, surgically implanting medical devices, utilizing physical sensors, or utilizing other measurement procedures;
3. Intervenes for research purposes with any human subject by manipulating the environment, such as controlling environmental light, sound, or temperature; presenting sensory stimuli; or orchestrating environmental events or social interactions;
4. Interacts for research purposes with any human subject, such as obtaining consent, engaging in protocol dictated communication or interpersonal contact, asking someone to provide a specimen by voiding or spitting into a specimen container, or conducting research interviews or administering questionnaires.
5. Obtains for research purposes identifiable private information or identifiable biological specimens *from any source* for the research. It is important to note that, in general, if an employee or agent obtains identifiable private information or identifiable specimens for human subjects research, they are considered engaged in the research, even if employee or agent does not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
 - a. observing or recording private behavior;
 - b. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; or
 - c. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

In general, the Federal [Office for Human Research Protections \(OHRP\)](#) considers private information or specimens to be individually identifiable as defined in the [Federal Regulations](#) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

In addition, review is required when research that can be defined by the [Federal Regulations](#) as human subjects research is conducted on campus, engaging Cal Poly agents, employees, or students, by

parties not directly affiliated with the University. Research that involves the use of Cal Poly non-public information to identify or contact human research subjects or prospective subjects must be approved by the IRB prior to initiating the research.

When is Review Not Required?

1. For classroom activities, demonstrations, and assignments unless the data will be collected and used in a systematic investigation that contributes to generalizable knowledge.
2. When an agent or employee of Cal Poly
 - a. Consults on research, but at no time obtains, receives, or possesses identifiable private information;
 - b. Performs commercial services for other investigators (or performs other non-collaborative services meriting neither professional recognition nor publication privileges), and adheres to commonly recognized standards from maintaining privacy and confidentiality;
 - c. Releases anonymous (no codes, links, or identifiers) individual information or specimens to another investigator (the data provider has no research component for the activity; if the data receiver has a research component then the project must be reviewed by the appropriate IRB); or
 - d. Releases identifiable private information to a state or local health agency for public health purposes (no research component to the activity);
 - e. Releases identifiable private information to an investigator when written permission of the subject has been obtained and is documented (the data provider has no research component for the activity; if the data receiver has a research component then the project must be reviewed by the appropriate IRB); or
 - f. Accesses information that is readily available to the public.
3. For studies conducted for the purpose of program evaluation, needs assessment, or quality control in which findings are solely intended for use in internal program planning and development and are not designed to contribute to generalizable knowledge.
4. For studies conducted by a University employee or student as a function of their independent consulting work or their work with another institution.
5. For studies in which humans participate but the information collected is not about the individual. For example, when the person who is interviewed/surveyed is asked to provide information specific to his/her expertise (technical information) as opposed to personal information about him/herself (opinions, perceptions); or when a person is asked to wear a device that will measure something external to the person (such as air quality) but no data are collected about the person.

The [Human Subjects Research Decision Chart](#) can be used to help determine if a project requires review by the Cal Poly IRB.

Determination of Risk Level and Type of Review Required

Risk is evaluated by the Cal Poly IRB based on the type, probability, duration, and severity of the risk that may or will occur during the research. Once these elements of risk have been evaluated, the anticipated benefits of the study are assessed to determine if the risk to benefit ratio is favorable. The IRB will determine whether the study meets the criteria or exceeds the parameters identified in the [Federal definition of minimal risk](#): “*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.” The IRB

evaluates risk and whether the proposed research exceeds minimal risk on a case-by-case basis with consideration to the procedures proposed and subject population to be involved in the research.

The IRB also must determine what type of review will be required. There are three classifications for review of human subjects research: minimal, expedited, or full. The [standard requirements for informed consent](#) (or its waiver, alteration, or exception) apply regardless of the type of review utilized -- minimal, expedited, or full.

The following categories, listed as exempt in the Federal Regulations ([45 CFR 46.101\(b\)\(1\)-\(6\)](#)), will typically be reviewed via a **minimal** review process:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as research on instructional strategies, curricula, or classroom management methods. *Note: This category cannot apply if non-exempt activities (per the Federal Regulations) are involved. See [paragraph below item #5](#) for more information.*
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior, provided (1) information is recorded in such a way that human subjects cannot be identified, directly or through identifiers linked to the subjects, AND (2) any disclosure of the subjects' responses outside the research could not place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Research involving educational tests, survey or interview procedures, or observation of public behavior may be considered exempt even if the provisions (1) and (2) listed above have not both been met if the subjects are elected or appointed officials or candidates for public office, or if federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. In addition, if the subjects are children, the exemption will not apply if the investigator participates in the activities being observed.
3. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or the information is recorded in such a way that subjects cannot be identified directly or through identifiers.
4. Research and demonstration projects designed to study, evaluate, or examine public benefit or service programs; procedures for obtaining benefits or services under public benefit or service programs; possible changes or alternatives to those programs or to the procedures; or possible changes in methods or levels of payment for benefits or services.
5. Taste and food quality evaluation and consumer acceptance studies, provided wholesome foods are consumed that have no additives, or include a food ingredient, agricultural chemical, or environmental contaminant at or below the level and for a use found to be safe by the [Food and Drug Administration](#), the [Environmental Protection Agency](#), or the [Food Safety and Inspection Service of the U.S. Department of Agriculture](#).

To qualify for minimal review, the proposed research must include *only* exempt activities (per the Federal regulations) and cannot involve any activities that are non-exempt, which encompasses all research with prisoners and some research with children. For example, if researchers are conducting research that involves surveys or interviews of children ([45 CFR 46.401\(b\)](#)), it cannot be considered exempt, even if it qualifies via the exemption for educational research. Also, if the research is exempt in all other categories but involves video, audio, or photographic recording, it also cannot be considered exempt, as the use of recordings for research purposes is listed as allowable in the [expedited list of categories](#) with no note that research in this category may be exempt. Also, sometimes research conducted in the school setting is not necessarily related to education practices: Federal regulations at [45 CFR 46.101\(b\)\(1\)](#) state “in established or commonly accepted educational setting, involving normal education practices.” Thus, a study of a non-

educational hypothesis in a school setting is it not necessarily considered exempt unless it qualified as exempt via all the other categories of exempt eligibility.

Projects that fall into one or more of the categories for minimal review status must be submitted to the IRB to confirm status and approve the protocol. The researcher will need to submit the required documents (see [The Review Process](#) below) to the Compliance/Information Officer. Approval from the IRB at the level of minimal review must be received by the researcher prior to initiating the research. Research conducted at Cal Poly that is approved at the level of minimal review is not exempt from the ethical guidelines of the [Belmont Report](#) or the Cal Poly [Policy for the Use of Human Subjects in Research](#), and approval may require additional protections in keeping with ethical standards.

Some projects reviewed via the minimal review process may be determined to be “exempt.” Typically, these projects involve the use of pre-existing, de-identified data, and the “additional protections” mentioned above may not be required.

Expedited review will be used when the proposed research procedures involve no more than minimal risk and only include procedures listed in one or more of the [Categories eligible for expedited review](#) listed below; or involve minor changes in previously approved (via full review) research during the period (one year or less) for which approval is authorized. A minor change is one in which, in the judgment of the reviewer, makes no substantial alteration in the a) level of risks to the subjects; b) the research design or methodology; c) the number of subjects enrolled in the research (no greater than 10%) of the total requested; d) the qualifications of the research team; e) the facilities available to support safe conduct of the research; or f) any other part of the research that would otherwise warrant review of the proposed changes by the convened IRB.

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 process when the specific circumstances of the proposed research involve no more than minimal risk to the subjects. The categories in this list apply regardless of the age of the subjects, except as noted.

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 subject’s financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human subjects.

Categories eligible for expedited review:

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 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 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, nonpregnant 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 nondisfiguring 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 HHS regulations for the protection of human subjects; 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; this listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows: 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 where no subjects have been enrolled and no additional risks have been identified; or 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.

An expedited review will be conducted by a subcommittee of the full IRB. The subcommittee for each expedited review will typically consist of a subset of two or three of the following IRB members: the IRB Chair, the Compliance/Information Officer, one or more IRB members with expertise related to the proposed research topic, and/or one member whose area of expertise is in a discipline other than that of the researchers. All members of the IRB will be apprised of all expedited review approvals by means of the agenda for the next scheduled meeting. Copies of the expedited review approvals will be made available for any optional review at the request of any IRB member.

Full review, or review by the convened IRB, will occur on all research projects that are not eligible for minimal or expedited review. Studies in which the risk is determined to be more than minimal will require review by the convened IRB.

The Review Process

The IRB reviews research involving human subjects to assure that the protocol meets with federal, state, and institutional regulations. Any activity related to human subjects research (including identification of potential subjects, recruitment, consent, etc.) may not be initiated until the study has been reviewed and approved. The ORED Human Subjects webpage has a [diagram which outlines the review process](#).

First Steps. The first step a researcher should take to request approval for a research project with human subjects is to review this document (*Procedures and Guidelines*) and also the Cal Poly [Policy for the Use of Human Subjects in Research](#). The information contained in these two documents, along with additional information on the [Human Subjects webpage](#), will assist the researcher in providing complete, timely, and accurate documentation needed to conduct the review. Consultations with the Compliance/Information Officer also are encouraged for clarification of any aspect of the review process, both prior to initiating a review and during the review. Advance consultations can often reduce the amount of time needed for the researcher to prepare the submission materials as well as the time for a proposal to receive approval. The Compliance/Information Officer is in the [Office of Research and Economic Development](#), Bldg. 38, Room 154, (805) 756-1508.

How and Where to Submit. The submission procedures are outlined below. All proposals for human subjects research must be submitted using [IRBManager](#), an online system for submitting and processing human subjects research activity. (Those who do not have access to computers or the internet should contact the Compliance/Information Officer for assistance.) Instructions for accessing IRBManager are found in [Using the IRBManager Online System \(pdf\)](#). These instructions will help users to login and begin submissions, but submitters also will need to be prepared with some documents that will be required:

- 1) Submissions for new projects will require attachments of
 - a. A research protocol. Information on what should be included in the protocol can be found in the section titled [Guidelines for Protocol Development](#)
 - b. Copies of documents that will be distributed to potential and enrolled subjects, such as recruitment materials, [informed consent/permission forms](#), surveys, and questionnaires. This also includes scripts or a written form of interview questions and verbal screening questions. The consent form is required for all projects where new data (not existing) will be obtained and used for analysis; sample consent form templates are available on [ORED Human Subjects Forms and Links webpage](#). The templates can be used as a starting point for creating a consent form, or forms, specific to each project. More specific information on the content of the consent form is in the [Guidelines for Protocol Development](#) section.
- 2) Submissions for modification requests of existing projects will require attachments of any documents that have been revised as a result of the proposed modifications.

Researchers who are uncertain as to whether their project would be reviewed via a [minimal review](#) process, as opposed to needing either an [expedited](#) or a full review, can consult with the Compliance/Information Officer prior to submitting the research proposal, but the online system will help guide you through this decision, too.

For projects that the researcher believes are eligible for [minimal review](#), the submitted research protocol can be *brief*, but should contain the information outlined in the [Protocol Development section of the Procedures and Guidelines](#). Researchers should generally allow one to two weeks for review of the proposal. The timing of approval will vary depending on the completeness of the proposal documents, number of submissions currently being processed, and staff availability.

If the researcher anticipates an [expedited](#) or a full review, a *detailed* research protocol should be provided, prepared in accordance with the [Protocol Development section of the Procedures and Guidelines](#). Every attempt will be made to provide feedback to the researchers as soon as possible but typically, for expedited reviews, about two to four weeks following receipt of the complete submission. Full reviews may require additional time, a month or longer, to provide the researcher with a response from the IRB.

Researchers should expect that there may be delays to expedited or full review proposals submitted during finals week, holidays, or quarter breaks, due to the academic schedules of the IRB members. Projects submitted for minimal review usually can be reviewed without delays during these periods.

As a project is being reviewed through the IRBManager system, researchers will receive emails with updates or instructions. If an instruction email is received, researchers **must** login into [IRBManager](#), access the relevant project, complete the action, and re-submit the online submission form. The emails will contain a link that will create direct access to the project to simplify the process. If the instructions are not followed, then the IRB office will not be able to complete the review and the project will remain inactive.

Guidelines for Protocol Development

Introduction. The purpose of the research protocol is to provide a clear and complete description of the purpose and benefits of the research, the methodology involved, the informed consent process, and any questionnaires, surveys, interview scripts or schedules, or other materials to be used. The reviewers will examine the protocol to determine if it can be approved using the criteria for approval of research. The protocol is the most important part of the proposed research submission as it outlines the specific procedures that will be followed during the course of the study. The protocol should be responsive to the information requested in each section below and written in terms that would be understandable to a reviewer who may be unfamiliar with the field of study. The protocol should be written in the tense (past, present, future) that is accurate at the time of submission of the protocol. Thus, future tense should be most common as the research should not have been initiated prior to obtaining the IRB's approval.

It is very important for researchers to review carefully Cal Poly's [Policy for the Use of Human Subjects in Research](#) and the other sections of this document for clarification of items mentioned here (e.g., the use of informed consent, vulnerable groups, experimental procedures) and to ensure that the research practices align with those guidelines.

It is *not* necessary to submit an entire grant proposal, senior project, or master's thesis proposal to the IRB. In particular, the IRB does not normally need to see your literature reviews, although a concise summary of the need for your research, its potential benefits, and your hypotheses is requested; and, it will be helpful to submit supporting literature to provide more information on potential risks and benefits. You may submit the methods section and relevant appendices from a senior project or a proposal. If they

do not contain all the information requested below, however, you must add that information to the research protocol you submit to the IRB.

Protocol Content. The protocol should include the following:

1. Title of the research project
2. Name and department/affiliation of the primary investigator(s) and faculty advisor (if applicable)
3. Statement of purpose, benefits, and hypotheses. This section need not be lengthy. In most cases, one or two paragraphs are likely to be sufficient. This statement should provide the hypothesis and summarize information on the study purpose/objective, the potential subjects, risk to benefit ratio, and how the data will be collected and maintained. (See [Criterion #1](#) and [Criterion #2](#) below.)
4. Methods. This section should be as detailed and lengthy as needed to include sufficient information (see section on [Specific Criteria for Approval of Research](#) below) to provide for thorough review. For [minimal review](#) projects, a brief form is usually all that is necessary, and for [expedited](#) or full reviews, a version with complete details should be provided. Often, delays in providing a timely response to a proposed research project arise when a reviewer has to request additional information and clarification, so researchers should carefully review their protocol to ensure that enough information is provided to avoid delays.
 - a. *Subjects and Subject Characteristics* (see [Criterion #3](#) and [Criterion #7](#) below). Provide information on the source (e.g., introductory psychology classes at Cal Poly or random sampling of public); selection and exclusion criteria (if applicable); approximate number; whether prospective subjects are members of a vulnerable group or not; expected age range; and other descriptors that might be relevant (e.g., gender, ethnicity).
 - b. *Investigator(s)* (see [Criterion #1](#) and [Criterion #2](#) below). Provide information on the identity of individual(s) who will administer the study, and relevant qualifications of s) (e.g., medical training when conducting physical tests)
 - c. *Materials and Procedures*. Include hardcopies, electronic attachments, or links to online sources that provide any recruitment materials, questionnaires, surveys or interview questions; descriptions of other materials or apparatus that will be used (see [Criterion #1](#) and [Criterion #2](#) below); chronological description of the procedures that will be followed in recruiting subjects, obtaining consent, and collecting and protecting the data (see [Criterion #1](#), [Criterion #2](#), [Criterion #4](#), and [Criterion #6](#) below); plan for data monitoring and subject safety (see [Criterion #5](#) below); and how participants will be debriefed (see [Criterion #8](#) below).
 - d. *Study Location*. Information on the location where the study will be conducted should be provided so that the IRB can determine the appropriateness of the setting (see [Criterion #1](#), [Criterion #2](#), and [Criterion #6](#) below). Also, special considerations associated with recruitment or data collection at the location (e.g., identifying potential subjects, location appropriate for obtaining informed consent, confidentiality and privacy concerns, etc.) should be detailed. If a questionnaire, or the study itself, will be conducted online, the researcher should provide information which satisfies the concerns regarding data security and confidentiality; the URL should be provided when applicable.
5. *Informed Consent Form* (see [Criterion #4](#), [Criterion #7](#), and [Criterion #8](#) below). The [Informed Consent Form](#) (or its related forms, such as Parental Permission and Minor Assent) must be used for all Cal Poly human subjects research projects, with a few exceptions (e.g., when pre-existing data is being analyzed or when informed consent waiver is requested). Informed consent is considered a process, not a singular event. Any changes that affect the consent documentation

must continue to be communicated to the subject for the duration of the subject's enrollment in the project. Consent from the subject must be sought by the researcher under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate, and minimize the possibility of coercion or undue influence.

6. *Debriefing Statement for Projects Involving Deception and Incomplete Disclosure* (see [Criterion #8](#) below); if applicable. In some behavioral research, incomplete disclosure or deception may be used for projects with no more than minimal risk, if complete disclosure or non-deception would impact the findings of the research. In these cases of deception or a lack of full disclosure, subjects must be subsequently debriefed. Debriefing procedures should include a written statement that will be summarized and then given to subjects for their records. Along with a description of the deception involved and an explanation about the true purpose of the research, the statement should also inform the subjects of their right to withdraw their data from the study and provide contact information for a referral in case the subject is upset or feels uncomfortable. This written statement should be submitted for review along with the [protocol](#) and [informed consent form\(s\)](#).

Specific Criteria for Approval of Research

Consistent with the principles outlined in the [Belmont Report](#), the [Federal Regulations](#), and the [OHRP Policy and Guidance](#), the following criteria will be used to evaluate research proposals at Cal Poly:

[Criterion #1. Risks to subjects are minimized](#) a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. Exposure of subjects to unnecessary risks is avoided, and precautions, safeguards, and alternatives are utilized to reduce the probability of harm and limit its severity or duration. An example of an appropriate safeguard is the presence of medically trained personnel during the administration of physical endurance tests*. The risks that must be identified and addressed include: (a) physical harm (e.g., pain, discomfort, injury, side-effects of drugs, dizziness), (b) psychological harm (e.g., stress, guilt, depression, loss of self-esteem, confusion, embarrassment), (c) social harm (e.g., the possible stigmatizing effects of diagnostic labels such as "delinquent" or "schizophrenic"), and (d) economic harm (e.g., threats to employment if a subject's involvement in research on HIV carriers or alcohol abusers were revealed). An additional risk involving social, economic, and/or psychological harm could result from having subjects reveal illegal activities. Some of the social and economic risks may be adequately addressed by appropriate procedures for maintaining confidentiality or anonymity. When relevant, referrals for assistance (e.g., counseling or medical treatment) or other appropriate efforts must be made to attempt to ameliorate any type of harm or distress that might be brought on, even in part, by the research.

**Required Procedures for Experiments Involving Vigorous Exercise, or Exercise of Subjects at Risk:* During these exercise protocols, at least two persons must be present at all times, one of whom is certified in CPR (cardiopulmonary resuscitation) techniques. Both persons should be prepared to call for appropriate medical assistance in the event that a subject requires it. Emergency telephone numbers should be posted in a clearly visible place in a testing facility. In addition, prospective subjects must fill out a standard health-screening questionnaire, such as the [PAR-Q \(Physical Activity Readiness Questionnaire\)](#), and these or similar criteria should be used to determine whether candidates may be enrolled in the study and/or whether a medical evaluation (release) should be required for participation.

[Criterion #2.](#) While a degree of risk may be unavoidable in some research, the **risks that are present must be reasonable in relation to anticipated benefits** of the research, including possible direct benefits to the subjects and the general benefits of the knowledge that may be gained from the research. The protocol should provide information on the possible direct benefits to the subjects and the general benefits

of the knowledge that may be gained from the research. Research design should be adequate and implemented to ensure that the results will be meaningful and, therefore, of potential benefit to increasing knowledge. Regarding studies of the direct benefit to subjects of an intervention or treatment method, investigators should offer the treatment or intervention to members of control groups if and when it has been found to produce beneficial results. Similarly, members of groups receiving alternative treatments that are determined to be less effective should be offered the more beneficial treatment as well. In evaluating risks and benefits, the IRB will 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 does not take into consideration any possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Considerations and Potential Problems:

Risk/Benefit Analysis. In weighing the potential risks against the anticipated benefits, the IRB will consider risks and benefits to the subject, the populations from which the subject was drawn, scientific knowledge, or society. If the IRB does not have enough information to be able to weigh the potential risks against the potential benefits, it will cause delays in review process, or a decision to not approve the project. If a project's potential risks outweigh the anticipated benefits, then the researcher will be asked to modify the protocol to reduce the risks or enhance the benefits, if possible. If it is not possible, the project will not be approved.

Research Design and Scientific Merit. The IRB's assessment will include a review of the research design, the scientific rationale, and the statistical basis for the structure of the investigation. The reviewers also will look at the specific aims of the research, the hypothesis to be tested, the questions to be answered, and the type of data to be gathered and tested. The IRB must determine that 1) the research uses procedures consistent with good research design; 2) the research design is sound enough to reasonably expect the research to answer its proposed question; and 3) the knowledge expected to result from the research is sufficiently important to justify the risk. If a research study is so methodologically flawed that little or no reliable information will result, it would be unethical to put subjects at risk or even to inconvenience them through participation in the study, and the protocol will have to be modified or, possibly, not approved.

Criterion #3. Selection of subjects is equitable considering the purpose of the research and the special needs of vulnerable populations. Equitable selection is intended to ensure that the burdens and benefits of research are fairly distributed. Researchers should exercise caution regarding the use of certain groups of subjects who are easily available, in a compromised position, or susceptible to manipulation. Voluntariness of participation could be diminished for prisoners or for students, patients, or employees of researchers, given that there may be an implied, if not overt, indication that treatment, grades, or employment status may be dependent on the individuals' willingness to participate in research. On the other hand, competent adults should not be overprotected and, thereby, excluded from research in which they might wish to participate. Thus, it should be especially clear in research proposals involving easily available subjects or those in a potentially compromised position, that appropriate measures are taken to ensure that their participation is not coerced in any direct or indirect manner. For example, if students constitute the subject pool, extra credit should only be offered for participation in research if at least one other equally attractive option for obtaining extra credit is also offered. Participation as a subject of research may not be a course requirement. In addition, while incentives for participation such as a few extra credit points or small monetary payments are generally allowable with appropriate informed consent, very large inducements may be inappropriate as they could be coercive, blinding prospective subjects to potential risks and reducing the voluntariness of their participation.

In studies of interventions for diseases or disorders to which women, minorities, or other specific groups might be susceptible, it is especially important that they not be underrepresented as subjects. In other

situations, however, researchers may need to take steps (e.g., screening interviews or questionnaires) to exclude certain groups of potential subjects if those individuals might be particularly vulnerable to the procedures implemented (e.g., pregnant women in studies of the effects of drugs or individuals with anorexic tendencies in weight loss studies). In the case of studies involving physical exercise, researchers should follow the health screening procedures and other recommendations provided in the current edition of [*Guidelines for Exercise Testing and Prescription by the American College of Sports Medicine*](#). It is recognized that some studies obviously require selecting prospective subjects only from specific groups that are relevant to the purpose of the study (e.g., children with learning disabilities in a study of the effectiveness of an educational intervention for such children).

Considerations and Potential Problems:

Subject Involvement. The protocol must provide adequate information regarding the subjects and their participation. The IRB will consider 1) whether or not the selection of subjects satisfies the ethical criteria of equitable selection, 2) whether or not the recruitment/enrollment process is coercive, and 3) whether or not the tasks that the subjects will be asked to complete, and the amount of time of participation will take, has been described in enough detail. Incomplete information, or information that indicates unequitable selection, coercive recruitment, or a high task/time cost in relation to benefits, will require the reviewer to request additional information or modifications, or possibly to disapprove the project.

Recruitment Methods and Access to Records. A primary concern of the IRB is that subject recruitment involves protecting the privacy and confidentiality of potential subjects. Recruitment procedures where names are released from private sources to an investigator are generally not approved; it is recommended that an organization or enrolled subject provide information about the study to the prospective subject, allowing the prospective subject to initiate contact. The IRB also cannot endorse practices where remuneration of any kind is provided for subject referrals or bonus payments made to members of the research team based on subject recruitment.

Questionnaires, Surveys, Interview Questions. The IRB will need to review all interview scripts and survey instruments, as part of the assessment of the research design. Draft versions may be submitted initially, especially if the project involves development of the questions as part of the research design, but final instruments (particularly for quantitative studies) must be approved prior to use of those instruments. Some interviews, or other qualitative projects, might have questions that are asked in response to previous answers. In that case, draft versions of the questions are acceptable, but if there are any substantive changes to the questions, they must be reported to the IRB as a protocol modification so that assessment of risk can be evaluated.

Criterion #4. Informed consent is sought from every prospective subject. A subject must provide consent, or a subject's legally authorized representative (e.g., a parent or guardian) must provide permission for children under the age of 18 or for individuals with diminished capacity to give their own consent (e.g., developmentally delayed adults). Informed consent should ensure that potential subjects or their legally authorized representatives understand the nature of the study and can knowledgeably and voluntarily decide whether or not to participate. Informed consent must be presented in a setting that does not create pressure or undue coercion to participate. Informed consent may not contain exculpatory language that attempts to waive the subject's or representative's legal rights or to release the investigator, research sponsor, or the institution from liability for negligence. [Section 46.116 of the Federal Regulations](#) lists the basic elements that must be included in each informed consent statement. Section 46.116 also contains additional elements that may be appropriate to include in informed consent statements in some studies, as well as a brief discussion of exceptions to the need to obtain informed consent or to include all of the basic elements of consent (e.g., a full disclosure of the nature and purpose of the study). See also the more-detailed section on [Informed Consent](#) in this document.

Full disclosure of the purpose of the study is not required at the onset of the subject's participation in studies with no more than minimal risk, if complete disclosure would render the findings of the research invalid. For example, a researcher could justifiably fail to inform subjects that their attention span will be

assessed as a function of the type of background music being played, given that that information could itself produce changes in the subjects' behavior (e.g., greater attempts to focus their attention in spite of distracting music). Deception (e.g., telling students their problem-solving ability will be tested when, in fact, they are being observed regarding their competitiveness), is similarly allowable in research of no more than minimal risk when the deception is methodologically necessary to test the desired hypotheses. In cases of deception or a lack of full disclosure, subjects must be subsequently debriefed regarding this information. See [Criterion #8](#) and [Guidelines for Protocol Development](#). An example of an allowable exception to the need to obtain informed consent is research involving only nonintrusive naturalistic observations of public behavior in which data are recorded in such a way that observed individuals cannot be identified.

The informed consent should be documented in a written and signed consent form containing the appropriate elements of informed consent. Each potential subject or legal representative should be given adequate time to read the consent form before being asked to sign it. **The consent form should be written in language easily understandable to the prospective subject or legal representative.** This implies that consent forms should be available in an appropriate language other than English for prospective subjects or legal representatives not fluent in English. It also implies that technical jargon, which may be familiar to the researcher but not necessarily to others, should be avoided or explained in the consent form. A signed consent form may be waived if (a) the only record linking the subject and the data would be the consent form and the principal risk to the subject would be harm that could result from a breach of confidentiality, and (b) no more than minimal risk is involved and the study involves no procedures for which written consent is normally required outside of the research context.

Considerations and Potential Problems:

Informed Consent and Debriefing Statements. If the protocol does not include informed consent forms and documentation, as well as any necessary debriefing statements, problems or delays can result. The documents will be reviewed to ensure that they contain the required elements and are free from spelling and grammar errors; non-compliant consent forms, permission forms, and debriefing statements will have to be modified.

Criterion #5. When appropriate, plans are included for **adequately monitoring the data** to ensure the safety of the subjects. Researchers are required to monitor their procedures carefully throughout the data collection process to reevaluate the risks to human subjects. If the risks are determined to be greater than initially predicted (e.g., an exercise protocol results in dangerous increases in heart rate), the IRB Chair or the Compliance/Information Officer should immediately be notified and prompt, appropriate steps should be taken to reduce the risks, obtain additional informed consent, and/or discontinue the procedures.

Criterion #6. **The privacy of subjects and confidentiality of data must be adequately protected.** **Privacy** refers to the subject's right to have control over the extent, timing, and circumstances of sharing him- or herself with others. Privacy is typically protected by informed consent which ensures that subjects have voluntarily agreed to share themselves with others. Maintaining **confidentiality** requires that researchers take steps to ensure that the information revealed by the subject is not divulged to others without the subject's permission. Information is regarded as *confidential* when the researcher *could* identify which data are associated with an individual subject but agrees not to reveal this information to others. **Anonymity** of subjects' responses is the most certain method of ensuring that the identity of a subject will not be associated with his or her data. When data are collected *anonymously*, even the researchers have no means by which they could identify which data belong to which subjects.

Considerations and Potential Problems:

Privacy and Confidentiality. The IRB will have to determine whether adequate procedures are in place to protect the privacy of the subjects and to maintain the confidentiality of the data. Problems may arise in approving projects that do not have clear information on the protections in place regarding privacy and confidentiality, or if the plan is not sufficient to ensure protection.

Data Safety and Monitoring. The protocol must indicate that the data will be securely managed, especially for projects involving more than minimal risk. In addition, data security must comply with Cal Poly's [Information Security policy](#). Generally, this means that data collected during research projects must be maintained on password-protected and encrypted computers or in locked cabinets. Also, there are additional concerns for projects conducted through online servers; more information can be obtained from the Information Security program.

See the section on [Confidentiality Concerns](#) for more detailed information.

Criterion #7. Additional safeguards have been implemented to protect the rights and welfare of special classes of subjects, particularly [subjects who might be vulnerable](#) to undue influence or coercion. When the potential subjects are children, prisoners, pregnant women, human fetuses, cognitively impaired persons, economically or educationally disadvantaged persons, college students, or employees, additional safeguards should be indicated in the protocol. One safeguard applicable to children and mentally disabled persons is the requirement of obtaining the informed consent of a legal representative of the prospective subject. The legal representative must be a competent adult whose primary concern in the research situation is the best interests of the prospective subject who is the representative's ward. Even when a legal representative gives informed consent for a ward to take part in a research project, the individual subject/ward must still give assent, or agreement, to participate as well.

Considerations and Potential Problems:

See the section on [Vulnerable Populations](#) for more detailed information. Missing information or inadequate protections will need to be addressed before the IRB will be able to provide a decision regarding approval.

Criterion #8. Adequate debriefing of subjects regarding the purpose of the study and any deception involved in the procedures is included. Subjects are offered a method of obtaining a summary of the research findings when available. For example, all subjects may be given a copy of the informed consent form which includes the name, business phone number, and business address of the researcher or advisor for the project and an invitation for interested subjects to contact that individual when it is expected that the results will be available. Alternatively, a summary of the results might be posted in a location accessible to the subjects, such as an information bulletin board in a gym at which athletes had participated in research on an exercise program. Such summaries, as well as other reports of findings, should, of course, refer to no subjects by name or other information that would indicate individuals' identities. In addition, when applicable, debriefing should include information on any deception that has been implemented. See [Criterion #4](#) and [Guidelines for Protocol Development](#).

IRB Meetings

The Cal Poly IRB will convene to review and approve projects not eligible for [minimal review](#) or [expedited review](#). Meetings are scheduled as least once per quarter (during the academic year) and/or as proposals which require review by the convened IRB are submitted. The schedule may vary depending on holidays or ability to establish a quorum. Quorum must be present for IRB decisions and is defined as: A simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area and one member in a scientific area.

All members present at a convened meeting have full voting rights, except in the case of conflict of interest. A member who has conflict of interest cannot vote but still counts toward establishing quorum.

IRB members must be present at the meeting, whether physically or via teleconferencing or videoconferencing. Pertinent documents are sent to all members prior to the meeting, usually at least a week prior, but the timeframe may be less if there are delays in receiving complete documentation. Opinions of absent members may be transmitted by electronic or written means and may be considered by the attending members, but may not be counted as votes or to satisfy quorum.

At the discretion of the IRB, the principal investigator(s) may be invited to attend the meeting to present the project and answer questions about proposed or ongoing research.

Records, correspondence, and meeting minutes related to IRB actions and activities are maintained in accordance with the Federal Regulations [45 CFR 46.115](#).

Review Decisions

Following the review of the researcher's materials, the Cal Poly IRB will provide a decision, regarding the project's compliance with ethical guidelines; outcomes may include: approval, approval with conditions, clarifications or changes required, insufficient information, or approval denied.

Approved Research. The project is approved as submitted and the researcher will receive notification.

Approved with Conditions. A conditional approval is awarded if there are correctable concerns. Correspondence will be sent to the researcher indicating the conditions, and once all the conditions have been satisfied, the researcher will receive notification. Projects approved with conditions are not considered active until the conditions have been satisfied, so researchers must comply with the conditions before recruiting or collecting data from human subjects. Included in this category is "Preliminary Approval," in which the sponsoring agency requires approval but the study procedures will be developed during the course of the project. For this type of approval, the researcher will be required to submit complete recruitment, consent, and intervention materials at a later date for a more complete review and approval before recruiting or collecting data from human subjects.

Clarifications or Changes Required or Insufficient Information. The project has substantive issues, or missing information, that will require correction or completion before the IRB can determine if approval will be provided. Correspondence will be sent to the researcher indicating the questions or concerns, and the researcher will be required to respond before a decision will be made regarding approval. Research may not commence until the stipulations have been addressed and notification of approval is issued to the researcher.

Approval Denied. The project has significant issues which make approval unwarranted. The researcher may not conduct the project, and the IRB will provide the rationale for the decision. The researcher may resubmit the project to the fully convened IRB if 1) the reasons given for disapproval can be corrected and addressed; or 2) the project was subject to only minimal or expedited review and the researcher would like the full IRB to provide the final decision. In order to appeal a decision, the researcher should submit a written justification of their request to the Compliance/Information Officer.

With any type of review or decision, a researcher is welcome to submit additional information to clarify the planned research practices at any point during the review process and may request to meet with the Compliance/Information Officer, the IRB Chair, the Dean of Research, or the IRB to discuss the decision on the research proposal.

An "approval denied" decision of the fully convened IRB is final; there are no other forms of appeal. Cal Poly administration cannot override a denial decision on a research project, but does have the authority to disapprove an approved project due to university issues, such as resources, policies, etc.

All decisions are provided in writing, via communications from IRBManager, to the researcher(s). Reports of the actions of the fully convened IRB are provided in the form of minutes, which are maintained by the Compliance/Information Officer.

Approved Research Compliance

Approval Period. At the time of initial and continuing review, the IRB will determine the length and terms of approval, appropriate to the degree of risk. The approval period will be up to one year, but may

be less if the IRB determines that a more frequent interval of review is required. This approval period is consistent for all projects, including those approved via the minimal review process.

To determine if a study will require a more frequent interval of review, the IRB will consider the following and document, in meeting minutes, the determined interval: The probability and magnitude of anticipated risks to subjects; the likely medical condition of the proposed subjects; the overall qualifications and specific experience (related to the proposed research) of the principal investigator and the other members of the research team; the nature and frequency of adverse events observed in similar research at this or other institutions; the novelty of the research making unanticipated problems more likely; and any other factors that the IRB deems relevant.

Commencement of Research. Subject recruitment and data collection should not be initiated prior to obtaining unconditional written approval from the IRB.

Modifications, Unanticipated Problems, and Adverse Events. The researcher must promptly report, via IRBManager, any alterations in their personnel, funding, materials, or procedures not addressed in their initial submission material, as well as any unanticipated problems, adverse events, or complaints regarding the research project.

Independent Verification Regarding Material Changes. In some cases, the IRB might be required to independently verify, utilizing sources other than the investigator, information about various aspects of the study. This could include adverse event reporting, information in the scientific literature, reports of drug toxicity, drug approval status, or that no material changes occurred during the designated approval period. The IRB will consider the following and document, in meeting minutes, these factors in order to determine which studies require independent verification: The probability and magnitude of anticipated risks to subjects; the likely condition of the proposed subjects; the probably nature and frequency of changes that may ordinarily be expected in the type of research proposed; prior experience of the investigator(s) and research team; and any other factors which are deemed relevant. In making these determinations, the IRB may prospectively require that the verifications take place at predetermined intervals, may retrospectively require such verification at the time of continuing review, or may require such verification at any time during the approval period in light of new information.

Termination of Approval. The IRB reserves the option of withdrawing approval of a project if circumstances warrant. For example, approval may be withdrawn if the research procedures are found to produce greater risk of harm than previously anticipated; if it is found that the research is not being conducted in adherence with the approved protocol; or if any modifications or adverse events are determined to have increased the risk.

Continuing Review of Active Projects (Extensions/Renewals)

Approved research is subject to continuing review at least yearly (or more frequently if specified by the approval decision). Generally, projects should not be submitted more than 30 days prior to the expiration date, but more time may be needed if the project renewal request will require review by the full IRB, or if there are modifications or adverse events to report. The review must take place before the expiration date; any lapse in approval can result in suspension of subject recruitment/enrollment and, if the research is sponsored, notification to the funding agency.

Automatic notifications of expiration dates will be sent to researchers by IRBManager. In addition, to assist researchers on sponsored projects, the [Sponsored Programs Office](#) will send out renewal notices in advance of the expiration date. However, it is always the researcher's responsibility to ensure that the extension is approved prior to the expiration date. Within IRBManager, projects that are not extended within 30 days of expiration will no longer be active; to continue a project that is no longer active will require a new submission by the researcher and a new approval from the IRB.

Continuing Review Process. Projects needing renewal must be submitted using [IRBManager](#); see the instructions on Continuing Review (on page 6 of [Using the IRBManager Online System](#)). The Compliance/Information Officer will either renew a project with no substantial changes, or refer it to the IRB (in whole or part) for a more intensive review, depending upon any reported problems, and/or level of initial review. Researchers should allow one to three weeks for extension/renewal approvals, but possibly longer for renewals requiring approval by the full IRB.

Review of Changes to Active Projects (Modifications)

Researchers working on approved projects must promptly report any modifications to the personnel, funding, materials, or procedures that were not approved in the initial submission materials. Modified procedures cannot be instituted and modified documents cannot be distributed until they have been reviewed and approved. If the proposed change is to eliminate an immediate hazard to a subject, advance approval is not required but the IRB must be notified *immediately*, so that the change can be reviewed to determine that it is consistent with ensuring the subjects' continued welfare.

Modification Review Process. Modification requests must be submitted using [IRBManager](#); see the instructions on Modification Requests (on page 5 of [Using the IRBManager Online System](#)). For projects originally reviewed as expedited or full, the review of the modifications will have to be referred to the IRB (in whole or part). For projects originally approved via a minimal review, the Compliance/Information Officer will either approve the modifications or refer the decision to the IRB. For research previously approved by the fully convened IRB, an expedited procedure may be used to review minor changes. When a proposed change is not minor (e.g., procedures involving increased risk or discomfort are to be added), then the IRB must review the modification request at a [convened meeting](#) before the change can be implemented. Modification request approvals may take one to three weeks, but may take substantially longer if review by the full IRB is required.

Unanticipated Problems, Adverse Events, and Complaints

Researchers are required to report to the IRB any unanticipated problems or adverse events, as well as any complaints they have received. In addition, complaints from subjects may be addressed directly to the IRB Chair, the Dean, or the Compliance/Information Officer. Unanticipated problems are those problematic incidences that were not anticipated to have occurred and were not addressed as a potential risk during the initial review; adverse events are those problematic incidences that were addressed as a potential risk. Serious problems or events – such as those resulting in serious injury or death – must be reported to the IRB immediately whenever possible or at least within 48 hours from the onset of the incident. Other, non-serious incidents must be reported within 5 business days.

Reporting Process. All reports of problems, events, or complaints must be submitted using [IRBManager](#); see the instructions on Reportable Events (on page 7 of [Using the IRBManager Online System](#)). The Compliance/Information officer will conduct an initial review and then, after consultation with the IRB Chair or Dean, will possibly contact the researcher for additional information or discussion, including whether or not measures have been put in place to remedy the problem. After determining the nature or seriousness of the problem, 1) the report will be routed to the Chair or Dean for immediate response; or 2) the report will be filed and provided to the IRB at the next meeting. The response from the Dean, Chair, or IRB could include – depending upon the seriousness of the problem – revisions to the consent form and/or protocol, or termination of approval. [Federal Regulations](#) also may require that the incident be reported to the OHRP.

Vulnerable Populations

Special populations or vulnerable subjects include [children](#), [pregnant women/fetuses](#), [prisoners](#), mentally disabled persons, economically or educationally disadvantaged persons, and subordinate individuals (e.g.,

students and employees). Additional safeguards to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence must be considered and included within the protocol, when necessary.

Research Involving Children. [45 CFR 46.401 Subpart D](#) 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 and is not legally emancipated. For research with children in other jurisdictions, such as foreign countries, the investigators may be asked to clarify the age of being an adult.

The IRB may only approve research involving children when all conditions of [45 CFR 46.401 Subpart D](#) 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). Only one parent or legal guardian needs to give permission, and assent from the subject should be obtained.

The research involves greater than minimal risk; however, the individual subject may receive direct benefit from participating in the research. Only one parent or legal guardian needs to give permission, and assent from the subject must be obtained.

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 permission of both parents, or legal guardian, is required, and assent from the subject must be obtained. (Both parents are required unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the custody of the child.)

The research, while otherwise not approvable presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Research in this category must be approved by the Secretary of Health and Human Services, and requires consent of either both parents, or legal guardian.

Involving Children in Research at School. The protocol should address whether class time is used or if the children will be participating outside of structured class time (also, address non-participating students, supervision of non-participants, procedures used to pull out children/subjects during class time, etc.) The protocol submission should also include a document, signed by a school administrator, indicating school permission to conduct the research on-site.

Wards. Federal Regulations provides guidance for children who are wards of the state, agency, institution or entity who can be included in research if: 1) the research is related to their status as wards; or 2) the research is conducted in settings in which the majority of children involved as subjects are not wards, such as schools, camps, hospitals, or institutions.

Parental Permission and Child Assent

Parental Permission. The IRB must determine that adequate provisions have been made for obtaining and documenting the permission of each minor's parent(s) or guardian. The permission document must include the required elements of consent (see Informed Consent Form in "[Guidelines for Protocol Development](#)" above), and any additional elements the IRB deems necessary. Depending on the level of risk and the type of benefit (indirect or direct), the IRB will need to determine and document whether permission should be obtained from one or both parents. The IRB also may waive the requirement for obtaining permission if:

1. the research meets the provisions for waiver ([45 CFR 46.116\(d\)\(1-4\)](#)) and the IRB determines that the protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children); and

2. an appropriate mechanism for protecting minors who will participate as subjects is substituted, and that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the subjects, and their age, maturity, status, and condition.

Child Assent. The assent process should be tailored to the age, maturity, and psychological state of the children involved and should be easy for the children to understand. The Cal Poly IRB recommends that minor assent wording be provided, at an appropriate comprehension level, in writing for older adolescents (15 or older), and verbally for those age 7-14; the assent of younger children should be obtained to the extent that it is possible in a developmentally appropriate way. Minor subjects must give positive assent, after the parent(s) or legal guardian has given permission, unless

1. the research will provide the prospect of direct benefit to the subject and which is available only in the context of the research (e.g., new therapy when none is available);
2. the subject is incapable, mentally or emotionally, of being reasonably consulted; or
3. the IRB specifically waives the requirement.

At times, there may be inconsistency between parental permission and child assent. A “no” from the child should be regarded as the desire of the child and can override a “yes” from a parent. There are exceptions to this guideline, e.g., if the research is examining the use of an experimental treatment for a life-threatening disease. Conversely, a child cannot be offered the opportunity to participate in the research if a parent has not provided permission.

Research Involving Pregnant Women, Human Fetuses and Neonates. [45 CFR 46.201 Subpart B](#) provides additional safeguards for research that involves pregnant women, fetuses (defined as the product of conception from implantation to delivery) and neonates (defined as a newborn).

Pregnant Women and Human Fetuses. Pregnant women or fetuses may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, pre-clinical 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;
2. 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;
3. Any risk is the least possible for achieving the objectives of the research;
4. 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;
5. 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, 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.
6. Each individual providing consent under paragraph 4 or 5 of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

7. For children who are pregnant, assent and permission are obtained in accord with the provisions of parental permission and assent;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

Neonates. Viable neonates may be included in research only to the extent permitted by and in accord with the requirements of research involving children. Viability, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. Nonviable neonate means a neonate that, although living, is not viable.

Neonates of uncertain viability and nonviable neonates maybe involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.
4. The requirements of items 5 and 6 below have been met as applicable.
5. *Neonates of uncertain viability.* Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the IRB determines that:
 - a. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
 - b. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
 - c. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with informed consent provisions, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
6. *Nonviable neonates.* After delivery, nonviable neonates may not be involved in research unless all of the following additional conditions are met:
 - a. Vital functions of the neonate will not be artificially maintained;
 - b. The research will not terminate the heartbeat or respiration of the neonate;
 - c. There will be no added risk to the neonate resulting from the research;
 - d. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
 - e. The legally effective informed consent of both parents of the neonate is obtained in accord with the informed consent provisions, except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to

meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

Research Involving, after Delivery, the Placenta, the Dead Fetus, or Fetal Material

Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

If information associated with material described in the paragraph above is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this guide are applicable.

Research Not Otherwise Approvable Involving Pregnant Women, Human Fetuses or Neonates

The Secretary of the Department of Health and Human Services (DHHS) will conduct or fund research that the IRB does not believe meets the requirements only if:

1. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and
2. The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:
 - a. That the research, in fact, satisfies the conditions of the Federal Regulations, as applicable; or
 - b. The following:
 - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
 - The research will be conducted in accord with sound ethical principles; and
 - Informed consent will be obtained in accord with all applicable informed consent provisions.

Research Involving Prisoners. As prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, the Federal Regulations provide additional safeguards for the protection of prisoners involved in research. The information in this section applies to all biomedical and behavioral research conducted under the Cal Poly [Policy for the Use of Human Subjects in Research](#). Even though the IRB may approve a research protocol involving prisoners, investigators are still subject to the administrative regulations of the [California Department of Corrections and Rehabilitation](#) and any other applicable state or local laws.

[45 CFR 46.301 Subpart B](#) allows the IRB to review and approve research that includes prisoners if the research falls into one of the following *permitted* categories:

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

3. Research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults). These types of studies -- if conducted or supported by DHHS -- may proceed only after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research; or
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which these studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study -- if conducted or supported by DHHS -- may proceed only after the Secretary of DHHS has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

In order to approve the research, the IRB must find that:

1. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
3. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
4. The information is presented in language which is understandable to the subject population;
5. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
6. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects of this fact.

Research involving prisoners cannot be reviewed via a minimal review process and must be reviewed via expedited or full board review. In addition, research with prisoners that is conducted or funded by DHHS or its agencies, after approval by the Cal Poly IRB, must receive OHRP authorization and DHHS Secretarial certification prior to initiating the research.

Research Involving Persons with Cognitive Impairments. Research involving subjects who are mentally ill or subjects with impaired decision-making capability warrants special attention. Cognitively impaired individuals must be able to make an informed choice to participate in the research; if the individual is not legally able to consent for him/herself, the subject's legal representative is authorized to determine whether or not the subject's participation in the study is appropriate. The IRB will review the protocol to determine if it includes information on how to determine subjects' capacity to consent, along with details of the consent process used to ensure that prospective subjects understand the information presented about the study. The IRB also will have to make sure that the subjects' vulnerability to coercion does not impact their ability to voluntarily participate.

Research Involving Persons who are Economically or Educationally Disadvantaged. The IRB will review the protocol to determine if the information presented via the informed consent process is appropriate for the education level of the potential subjects; and/or not exploit the subjects' potential vulnerabilities to coercion.

Research Involving College Students. The IRB will review the protocol to assess situational or unintended coercion. Recruitment procedures should create opportunities, but not pressure, to participate. If course credit or extra credit is provided as an incentive, an equitable alternative to earn credit should be offered. The IRB also will have to evaluate the proposed data collected and links to identity to ensure that there can be no impact on status (e.g., grades).

Research Involving Employees. The IRB will review the protocol to assess coercion, undue influence, and issues of confidentiality. Recruitment procedures should create opportunities, but not pressure, to participate. Researchers should provide information on how they will ensure the voluntary nature of participation if the subjects are recruited by the employer or the researcher is sponsored by the employer.

Confidentiality Concerns

The investigator is responsible for protecting information obtained from subjects to avoid unintentional access by others. Subjects should be provided with information, via informed consent, about the procedures used to protect confidentiality. The IRB may determine that documentation of informed consent be waived if this process (collecting signatures and maintaining copies) increases the risk of a breach of confidentiality.

Sensitive Data and Certificates of Confidentiality. If the data are considered to be sensitive (e.g., sexual preference or practices, use of alcohol or drugs, illegal conduct, mental health records, etc.) or place the subjects at legal risk, elaborate measures to protect confidentiality may need to be implemented. In some cases, a Federal Certificate of Confidentiality may be issued to protect sensitive data from being subpoenaed by a court of law.

Required Reporting. State law and mandated reporting requirements may limit the extent to which investigators are able to protect subjects' confidentiality. If the subjects are likely to disclose illegal or dangerous behavior (e.g., a subject reports any kind of abuse or serious harm to self or other), the investigator should include a description of the limits to confidentiality in the consent form.

Methods to Protect Confidentiality. Appropriate measures to achieve confidentiality include: limiting the personal information recorded to that which is essential to the research; removing face sheets containing identifying information from questionnaires; substituting code numbers for names or other identifiers; limiting the number of individuals with access to data containing identifiers; and storing data in locked cabinets, or if stored electronically, on computers which are encrypted and password-protected. If codes are used and a list matching the codes with the identity of the subjects is maintained, the list must be kept in a secure location separate from the data.

Audio/Video Recordings and Photography. If a study involves the use of audio or video recordings, the protocol should include information on where a subject's image or voice will be presented and to whom. The subjects should be informed, via informed consent, of how the recordings will be used. If the investigator would like permission to use the recording for a purpose other than the specific research, an addendum to the informed consent (such as an Audio/Video Release Form) should be used to obtain authorization. In addition, protocols that include audio/video recordings should indicate where and how the recordings will be stored and also how long they will be retained before being destroyed, if applicable.

Data Storage, Retention, Disposition and Transportation. In order to further protect subject privacy, the protocol and informed consent should include information on where and for how long research records will be stored, and who will have access to study data. The IRB will also review procedures used to dispose, upon completion of the study, of research records, samples, and specimens. If data is to be

transported (physically or electronically), the protocol and informed consent should include procedures to ensure that the data will be transported in a manner that minimizes risks associated with the inadvertent loss or theft of data.

Additional Issues. More complex privacy issues are involved in studies that use private records (such as medical records) to identify prospective subjects and in some observational studies (e.g., those in "quasi-public" places such as hospital emergency rooms); those undertaking this type of research should consult with the Compliance/Information Officer or the Chair of the IRB.

Costs and Incentives

The proposed protocol and informed consent form should include relevant information on costs to subjects related to their participation, and any compensation or incentives they will receive for their participation.

Costs. Any anticipated or actual costs for participation in the research must be described, via informed consent, to prospective subjects. If the study involves the potential for injury or illness, the consent form and the protocol should state how costs related to medical care will be covered and by whom.

Compensation and Incentives. To assist with subject recruitment, incentives may be offered. The IRB will consider the appropriateness of the incentive level/amount, making sure it is reasonable compared to the burden or inconvenience incurred by participants. The amount and type of the incentive should not coerce or unduly influence the prospective subject into participating. The protocol and informed consent should clearly state what incentives are being offered, under what terms the incentive will be provided, and if receipt of the incentive is contingent on completion of the study. Incentives may be described on recruitment materials, but should not be sensationalized or exaggerated.

Use of a prorated incentive payment system may be appropriate in some cases. This type of system allows for subjects to be paid as the study progresses and does not create the perception of penalty for discontinuing participation; however, if complete data sets (i.e., all sessions, interviews, surveys, etc.) must be acquired to draw any conclusions (related to proposed benefits), the IRB can consider one-time, end-of-study incentive payments.

The method of providing incentives must be described. Common methods are cash, gift card, non-monetary gift, or coupon. If the incentive payment is processed via a record keeping system (e.g., checks or electronic transfer), the payment data (e.g., name, address, social security number, amount paid) must be maintained separately from the research data, in order to not compromise confidentiality.

Lotteries and Raffles. A lottery or raffle incentive involves conducting a random drawing in which one or more individuals receive an incentive. According to the California Department of Consumer Affairs, "California law prohibits lotteries. A lottery is any scheme for the disposition of property by chance among persons who have paid or promised to pay any value for the chance of obtaining the property, with the understanding that it will be disposed of by chance." (There are three exemptions to this prohibition including the California State Lottery, bingo for charitable purposes and a raffle conducted by a non-profit, tax-exempt organization for charitable purposes.)

Courts have used certain rules to decide whether a scheme includes consideration because it is not always clear. If a person is eligible to win a prize without purchase, this is no consideration and the contest is legal. If some people may pay money – for example, an admission charge or buy a product – there is not necessarily consideration if others may enter the contest without such a purchase. If eligibility to win a prize is limited to those who have paid money, however, there is consideration and the contest is not legal.

Consideration in the context of research applies when subject compensation is a lottery or raffle to win a prize (e.g., gift certificate, iPad, etc.). If eligibility to win a prize is limited to those who participate in the research there is consideration therefore the contest is not legal.

To use raffles/lotteries as incentives the following must apply: a) the project's procedures ensure that any individual who is asked to participate in the research study but declines, who consents/assents to enroll in the study, or who fails to complete the study, will be given equal compensation by having an equal chance of winning. In other words, if an individual is eligible to participate in the study, and therefore the lottery, raffle and/or drawing, they are not required to participate in the study to be eligible to participate in the lottery, raffle, and/or drawing; b) there are procedures for the inclusion of an individual who is not asked to participate in the study but wishes to be included in the lottery, raffle, and/or drawing; c) that there is a fair method of choosing the winner and how the winner will be notified; and d) that the approximate chance of winning (e.g., no less than 1 in 1000) is disclosed in the consent/assent.

If a lottery incentive is used, the protocol and consent form should also include an estimated timeline for when the information about the drawing will occur, how the person will be notified, how many prizes will be offered, and that an individual is not guaranteed to win any prize. This information should not only be included in the informed consent form, but also provided to those who enter the lottery without participating in the research.

If lottery prizes are provided as an incentive for studies where the data is collected anonymously (or where identity is not linked to responses), the contact information for the subjects' entry into the lottery must be maintained separately from the research data.

Informed Consent Guidance

Sample informed consent forms, including parental permission forms, can be found on the Cal Poly IRB [Forms and Links](#) webpage. The [standard requirements for informed consent](#) (or its waiver, alteration, or exception) apply regardless of the type of review utilized -- minimal, expedited or full. The *required* elements of informed consent are defined by the [45 CFR 46.116](#) and must include:

- Identification of the activity as research;
- name(s) of the researcher(s);
- purpose(s) of the study;
- expected duration of the subject's participation;
- summary/description of the procedures;
- notification of any experimental procedure(s) -- meaning procedures not yet accepted as standard practice such as experimental drugs -- that may be used (if applicable);
- disclosure of alternative treatments (if applicable);
- foreseeable risks or discomforts (physical, psychological, social, or economic as *described in [Criterion #1](#) and [Criterion #2](#) above*);
- benefit(s) to subject or others;
- incentives (*see section above on [Costs and Incentives](#)*) (if applicable);
- how confidentiality will be protected and records maintained;
- recourse if injury occurs (if the study is deemed of greater than minimal risk);
- referral(s) to services that might assist them with any distress generated by their participation (e.g., a referral to the campus Psychological Services for students answering a questionnaire on sexual assault);
- indication that their participation is voluntary and that no penalty or loss of benefits (to which the subject is otherwise entitled) will result from their refusal to participate or their discontinuing their participation once initiated;
- referral for questions or to report harm or to obtain a summary of the study's results (e.g., the name and campus phone number of the faculty member conducting or supervising the project);
- offer of a copy of the consent form; and
- contact information for the Chair of the IRB and the Dean of Research.

To keep informed consent forms an appropriate length, required elements do not have to be included if they are not applicable to the study. For example, do not include information on incentives if there are none: The informed consent form does not have to state “There are no incentives for participation.”; the topic can be excluded.

In addition, these other elements may be included, as appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subjects is or may become pregnant), which are currently unforeseeable;
- anticipated circumstances under which the subject’s participation may be discontinued by the researcher without regard for the subject’s consent;
- any additional costs to the subject that may result from participation in the research (*see section above on [Costs and Incentives](#)*);
- the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- a statement that significant new findings developed during the course of the research, which may relate to the subject’s willingness to continue to participate, will be provided to the subject; and/or
- the approximate number of subjects involved in the study.

In addition to providing the information above, the informed consent process also must be documented in written form (*see [Criterion #4](#) above*) – the forms must be signed* by the subject or the subject’s legally authorized representative, and a copy given to the person signing the form.

Informed consent documents can be presented orally, but a short form written consent document, stating that the elements of informed consent have been presented orally to the subject (or the subject’s legally authorized representative) should be read and signed. When this method is used, there must be a witness to the oral presentation, and the IRB will need to approve a written summary of what is to be said to the subject and also the short form document. Only the short form is signed by the subject, but the witness will sign both the short form and a copy of the written summary. Copies of both documents are given to the subject.

**A separate signed informed consent form may not be appropriate in studies in which the only link between the data and the subject's identity would be the signed consent form; or that the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context. In this case, the informed consent information should still be presented in writing (with a copy provided), though not on a signed form. See the sample on the Forms webpage for “Anonymous” informed consent.*

Informed Consent for Minor Subjects. When the subjects are children, informed consent is provided via use of a Parental Permission Form and Minor Assent (*see [Criterion #7](#) above*). The requirements of parental permission are that one signature is sufficient unless [45 CFR 46.408](#) stipulates that both parents must sign. Minor assent should be presented writing for older adolescents (15 or older), and verbally for those age 7-14; the assent of younger children should be obtained to the extent that it is possible in a developmentally appropriate way.

Informed Consent for Research Not Conducted In-Person. When the data are to be collected via online methods, or via telephone or other electronic forms of communication, informed consent still must be obtained and documented. A written consent form must be prepared and a method must be developed for providing a copy to the subject. For online surveys, the consent form should be the first page of the survey, the consent form should indicate that the subject should print a copy, and there should be “buttons” that would allow the subject to consent (and enter) or refuse (and exit) the survey. For telephone -- or other types of “virtual” -- interviews, the consent form should be sent electronically or via hard copy to the subject and read orally prior to beginning the interview. If a signature is required, then the signed copy should be returned to the researcher and a copy retained by the subject.

Waiver of Consent Requirements. [45 CFR 46.116](#) allows that sometimes waiving the informed consent requirement can be allowed or the required elements can be altered. To do so, the following must apply, either:

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

In addition, it is possible that the requirement for parental permission can also be waived 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 (for example, neglected or abused children), 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.

Informed Consent for Non-English Speaking Subjects. If the potential subjects cannot read English, the researcher should submit both the English form of the consent form, as well as a translated form in the appropriate language, to the IRB for review. It is acceptable to submit the English form first, and then provide the foreign language version at a later date, after any revisions to the English form have been incorporated.

Investigator Responsibilities

Protecting the rights and welfare of research subjects is a shared responsibility of the IRB and principal investigators (PIs). Ultimately, PIs are responsible for the conduct of the research and the adherence to the regulations and policies governing human subjects research. PIs may delegate research responsibility; however, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate. This applies to PIs on all projects approved by the Cal Poly IRB.

PIs who conduct research involving human subjects must:

- develop and conduct research that is in accordance with the ethical principles in the Belmont Report
- develop a research plan that is scientifically sound and minimizes risk to the subjects
- have sufficient resources necessary to protect human subjects, including supervision, a sufficient number of appropriately trained staff, and appropriate support services
- protect the rights and welfare of prospective subjects and enrolled subjects
- have plans to monitor the data collected in regards to the safety of the subjects
- have a procedure to receive complaints or requests for additional information from subjects and respond appropriately
- ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating faculty and research staff
- obtain and document informed consent as required by the IRB and ensuring that no human subject is involved in the research prior to obtaining their consent
- ensure that all research involving human subjects is reviewed by the IRB and receives approval, in writing, before commencement of the research
- comply with all IRB decisions, conditions, and requirements

- ensure that protocols receive timely continuing review and approval by the IRB
- report unexpected problems or adverse events to the IRB
- obtain IRB review and approval, in writing, before changes are made to approved protocols or consent forms
- seek IRB assistance when in doubt about whether proposed research requires review.

Investigator Experience. In reviewing proposed research, the IRB will consider the PI's experience in the area of research to be undertaken to ensure that the research will be carried out appropriately. The protocol should include a brief summary of the investigator's relevant research experience and training. If the investigator is a student, all student-initiated research involving human subjects must be supervised by an authorized faculty member; the IRB might also consider the qualifications and relevant experience of the faculty advisor in reviewing student-initiated research.

Conflict of Interest. All researchers must follow the [Cal Poly Conflict of Interest Policy](#). Researchers must identify for resolution under that policy's specific procedure any conflict of interest associated with the study, including, but not limited to, their personal (including spouse or dependent child) investment in or other financial relationship with a company that is sponsoring the study or that might profit from the study. If the researcher is permitted to proceed with the study following review under that policy, the research consent form provided to subjects should include an appropriate description of any relationship that might be perceived as a potential conflict of interest. If the conflict of interest status of a researcher changes during the course of the study, the individual is required to declare this to the IRB.

Training for Investigators. At Cal Poly, researchers and their research teams who will carry out federally funded research involving human subjects, that is not "exempt from further review" under Federal Regulations, are required to receive authorized training in the ethical principles and procedures for carrying out such research. Federal funds will not be awarded without proof of this training. A subscription to training authorized by the OHRP is maintained by Cal Poly and available online at the [CITI training website](#). It also is recommended that PIs and their research teams complete the training for funded projects that are determined to be "exempt from further review," or for non-federally funded projects that were approved via expedited or full review, especially in the cases where there is more than minimal risk, vulnerable populations, or potential risk to status of subjects should confidentiality be breached.

Investigator Concerns. Investigators who have concerns or suggestions regarding Cal Poly's human subjects research program, including this procedures and guidelines document, should convey them to the IRB Chair, Compliance/Information Officer, or Dean of Research, as appropriate. The appropriate entity will research the issue, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted.

Faculty Advisor's Responsibility when Supervising Student Research. Student-initiated human subjects research, whether senior project, thesis, or other types of research projects, must be supervised by a faculty member to ensure compliance with policy, procedures and regulations related to the protection of human subjects. In addition to his/her own responsibility for understanding the policies, procedures, and regulations, the faculty member also is responsible for providing guidance and mentoring to student researchers for the same. The faculty advisor should assist in protocol development; monitor study progress, including protocol compliance; and assist the student in handling research-related problems, including adverse event reporting.

Internet Research

Research conducted in the virtual world of the Internet is subject to the same review process, ethical concerns, and human subject protections as research conducted in the physical world. The main concerns of the Cal Poly IRB regarding human subjects involved in Internet-based research are informed consent, and protection of privacy and confidentiality. Informed consent language must include the required

elements; the protocol will be reviewed to determine what the expectation of privacy might be depending on the (virtual) location; and what measures are in place to maintain confidentiality. These concerns pertain to survey, observational research, and interventional research conducted with human participants virtually on the Internet or using electronic media.

Regarding observational research, the IRB will have to review the protocol to determine if the subjects have a reasonable expectation for privacy, if there is any deception involved, and/or if informed consent is required or can be waived; if consent is required, alternate methods of obtaining consent may have to be considered. In managing confidentiality in observational research, in addition to the typical requirements, the researcher(s) should also indicate how their confidentiality plan is in accordance with the confidentiality and privacy requirements of the site where data is being obtained.

In addition, data safety must be managed in accordance with the [Cal Poly Information Security Standards](#). Guidelines involving human subjects research conducted on the Internet are continuing to evolve as this type of research becomes more prevalent. As each project is unique, reviews will be tailored to address the specifics of the project.

Noncompliance

All human subjects research conducted under the purview of the Cal Poly IRB must comply with the Cal Poly [Policy for the Use of Human Subjects in Research](#), and will be reviewed in accordance with this procedures document. Researchers or protocols that do not comply with the Cal Poly Policy or Federal Regulations may be determined to be non-compliant and action taken to correct the non-compliance. Non-compliance may be minor or sporadic, or it may be serious or continuing:

- Minor or sporadic non-compliance is defined as failure to comply with Cal Poly [Policy for the Use of Human Subjects in Research](#) and the procedures provided in this document, and which in the opinion of the Chair and Compliance/Information Officer are administrative in nature. Examples of minor or sporadic non-compliance could include delays in providing required materials, including adverse event reports or revised documents.
- Serious non-compliance is defined as failure to follow any of the regulations, policies, and procedures described in the Cal Poly [Policy for the Use of Human Subjects in Research](#) and this document, and which, in the judgment of the Chair or the convened IRB, increases risks to participants, decreases potential benefits, or compromises the integrity of the human subjects research protection program. Research being conducted by any investigator (applicability as defined in the Cal Poly [Policy for the Use of Human Subjects in Research](#)) without prior IRB approval might be considered serious noncompliance, especially if the lack of review has placed the subjects, the researchers, or the University at a more than minimal risk.
- Continuing non-compliance is defined as a pattern of non-compliance that, in the judgment of the convened IRB or Chair, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

If, in the judgment of the Chair and the Compliance/Information Officer, the non-compliance is not serious, not continuing, and the proposed corrective action plan seems adequate, no further action is required. If, in the judgment of the Chair and Compliance/Information Officer, the non-compliance is serious or continuing, a formal inquiry will be held. If, in the judgment of the Chair and Compliance/Information Officer, any report or allegation of non-compliance warrants suspicion or termination of the research before completion of any investigation or inquiry to ensure protection of the rights and welfare of the participants, the Chair may terminate or suspend the research as described below, with subsequent review by the convened IRB.

Unreviewed Research. In the event that the IRB determines that research with human subjects, under the applicability defined in the Cal Poly [Policy for the Use of Human Subjects in Research](#), is or has been

conducted but which has not been submitted for review and approval by the Cal Poly IRB, the IRB will, as appropriate, report the non-compliance to those who need to be informed. This would include, but is not limited to: the investigator, the appropriate faculty advisor or mentor, the department chair, or college dean.

Suspension or Termination. The IRB may suspend or terminate approval of research that is not being conducted in accordance with the Cal Poly IRB's requirements or that has been associated with unexpected serious harm to subjects. In addition, non-compliance with the Cal Poly [Policy for the Use of Human Subjects in Research](#), the Cal Poly *Procedures and Guidelines for Human Subjects Research* (this document), and the [Federal Regulations](#) may result in additional sanctions imposed by the IRB, Cal Poly administration, the project sponsor, or Federal agencies or departments, as appropriate.

When approval is terminated by the Cal Poly IRB, in addition to stopping all research activities, any subjects currently participating will be notified that the study has been terminated and the procedures for withdrawal of enrolled subjects should be developed in consideration of the rights and welfare of the subjects. If follow-up of subjects for safety reasons is permitted or required by the IRB, the subjects will be informed of such, and any adverse events/outcomes will be reported to the IRB and the sponsor, if applicable.

Researchers should also be aware that, in general, Cal Poly *indemnifies* them from liability for adverse events that may occur in Cal Poly studies that are approved by the Cal Poly IRB. Failure to follow approved procedures may compromise this indemnification and make the investigator and/or faculty advisor *personally liable* in such cases.

Reporting. Unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with regulations or the requirements or determinations of the IRB, and suspensions or terminations of IRB approval must be promptly reported, as applicable, by the IRB and the Cal Poly Compliance/Information Officer to the:

1. Institutional Official;
2. researcher's department chair and dean, as appropriate; and
3. the [OHRP](#) and any sponsoring department or agency head.

Authority and Assurance of Compliance

At the delegation of the Provost and Executive Vice President for Academic Affairs, the Vice President for Research and Economic Development at Cal Poly has designated the Dean of Research as the responsible Institutional Official (IO) for oversight of the university's human research protections program. Cal Poly holds a Federalwide Assurance (FWA), FWA00000342, which is granted to IRBs that register with the OHRP.

Conduct of Quality Assurance/Quality Improvement Activities for IRB Operation

The Dean of Research, as the Institutional Official and through appropriate mechanisms, will monitor and review the processes and procedures of the IRB, including this document, to ensure effectiveness, efficiency, and compliance with both Federal Regulations and the Cal Poly [Policy for the Use of Human Subjects in Research](#). The Cal Poly [Office of Research and Economic Development](#) will conduct investigations and audits of ongoing research when the IRB directs an audit to be conducted or a complaint or allegation of non-compliance is received.

Board Member Appointment

The Cal Poly IRB has been established in accordance with the requirements of the current Federal Regulations, under 45 CFR 46.107.

The IRB members and the chair are appointed by the Dean of Research. IRB members who are faculty should be tenured, so as to avoid pressure or influence from more senior faculty or administrators. Due to the level of experience and relevant expertise needed to perform IRB duties, there are no term limits for IRB members, and they will continue to serve as long as they demonstrate knowledge of regulations, an understanding of the application of the ethical principles, and have time available to devote to the associated responsibilities. The Dean of Research will conduct annual reviews of the chair, IRB members, and IRB composition for compliance with Federal Regulations and Cal Poly policy and procedures, and will determine and seek action if a conclusion is made that a member's participation should be discontinued. If it is necessary to add new or replace exiting members, several methods are used to identify candidates: the existing members may be asked to provide recommendations; faculty with expertise in areas specific to the types of projects reviewed may be contacted directly; open calls will be announced via campus websites and distributed emails; interested persons may contact the Dean of Research to express interest; or the Dean of Research may identify and recruit potential members.

A list of current IRB members is available from the Office of Research and Economic Development, Bldg. 38, Rm. 154; (805) 756-1508.