SACRAMENTO STATE

Investigator Guidance:
Preparing Research for IRB Review

Office of Research, Innovation, and Economic Development
Research Integrity and Compliance

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Contents

I. Ethical Framework

A. Purpose of the IRB

The Sacramento State IRB's primary responsibility is to ensure that the rights and welfare of human subjects participating in research under the auspices of Sacramento State or their agents are protected. Toward this aim, the IRB is charged with ensuring that human subjects' research is conducted ethically and in compliance with federal regulations and the IRB procedures, available here: https://www.csus.edu/compliance/research-integrity-compliance/human-subjects-research.html

B. The Belmont Report

The Belmont Report contains three basic ethical principles central to human subjects research that guides the IRB in assuring protection of the rights and welfare of research subjects. These three principles are:

> Respect for Persons recognizes individual autonomy. Respect for Persons is demonstrated by obtaining informed consent, protecting privacy and confidentiality, and enacting additional protections for vulnerable populations.
>
> Beneficence requires that possible benefits of the research are maximized while the possible risks are minimized for the human subjects.
>
> Justice is demonstrated by the equitable selection of subjects with regard to the distribution of burden and benefit.

II. Definitions

A. Research

The Department of Health and Human Services (DHHS) Code of Federal Regulations (45 CFR 46.102(l)) has defined research as, "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." As described in the Belmont Report, "...the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).

The regulations also note items that do NOT fall under the definition of research: Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

1. Generalizable Knowledge

The IRB considers generalizable knowledge to mean drawing conclusions, facts, or principles derived from particulars (individual subjects, medical records, etc.) that are applicable to or affect a whole category (members of a class, kind, or group, a field of knowledge, etc.) and enhance scientific or academic understanding.

The majority of scholarly work in academia is intended to be shared, published, presented to colleagues, and is intended to have an impact (theoretical or practical) on others within one's discipline. Activities

that are disseminated with the intent to influence behavior, practice, theory, future research designs, etc. are contributing to generalizable knowledge.

2. Pilot Studies

As defined by Federal Regulation, research is a "systematic investigation, *including research development, testing and evaluation,* designed to develop or contribute to generalizable knowledge" (emphasis added). Pilot studies are an integral part of the broader research study and begins the path to hypothesis testing. In other words, there is intent to eventually develop or contribute to generalizable knowledge. These studies must adhere to the same review IRB requirements to protect human subjects, regardless of the number of subjects involved.

If the pilot study does not involve human subjects, the activity does not require IRB review.

3. International Research

IRB determinations and approvals of research applies to the investigator, not the location of the participants. An activity conducted by a U.S. investigator that occurs outside of the United States is still subject to U.S. regulations and may also be subject to international regulations. Sacramento State investigators planning to conduct research outside of the country must receive IRB approval prior to conducting the study.

B. Human Subject

A human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens" (45 CFR 46.102(e)(1)).

An *intervention* includes physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. An *interaction* includes communication or interpersonal contact between investigator and subject. This includes in-person, by phone, email, text, social media, etc.

For a study to be considered human subjects research, the data obtained must be **about** the living individual. In some cases, a researcher may interact or intervene with a living individual, but the purpose is to obtain data about a topic other than the individual (i.e. office procedures). These studies may not be considered human subjects research. See Research Not Involving Human Subjects.

C. 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" (45 CFR 46.102(j)).

1. Vulnerable subjects and protected populations

The Sacramento State IRB will follow the federal policy of assessing the purposes of the research and the setting in which the research will be conducted when it involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making

capacity, or economically or educationally disadvantages persons. The IRB may also determine that certain populations require additional safeguards due to their protected status, such as DREAMers or DACA individuals. This classification can be determined by the IRB when necessary.

D. Not Human Subjects Research

The definition of research specifically excludes the following activities:

(1) Scholarly and journalistic activities
   a. Oral history
   b. Journalism
   c. Biography
   d. Literary criticism
   e. Legal research
   f. Historical scholarship
   g. Public health surveillance activities by a public health authority
   h. Research activities authorized by law or court order solely for criminal justice/investigative purposes

This does not excuse the listed activities from following discipline specific ethical guidelines.

E. Additional Situations when IRB Review May Not be Necessary

1. Assisting a Researcher

If a Sacramento State affiliate is asked to help a researcher for recruitment or space to conduct a study, they may not be engaged in the research or require IRB review. One is only considered to be engaged in the research when obtaining consent from participants, collecting data from or about participants, and/or analyzing private identifiable data for research purposes.

2. Program Evaluation, Needs Assessment and Quality Control

Studies conducted for 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 are not subject to IRB review.

When the evaluation is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective *and will be shared as a program that can be used elsewhere (i.e. generalizing the outcomes for broader implementation)*, the activity is research.

When the purpose of an activity is to assess the success of an established program in achieving its objectives and the information will be used to improve that program, the activity is not human subjects research. **Publication does not make the activity research.** Data may be published and/or used for research purposes in the future and will be the responsibility of the person intending to use the data for research to obtain IRB approval, *if data are identifiable*.

3. External Investigator

Persons not affiliated with Sacramento State who plan to conduct research that involves the use of Sacramento State facilities or affiliates should provide a copy of their IRB approval letter to whomever they are contacting to gain access to the campus. Documentation can be sent to the Research Integrity and Compliance Officer for official verification, although this verification may be completed by other campus

personnel. The Sacramento State IRB may choose to review the study to ensure ethical practices are implemented when conducting the research. Please view the Cooperative Research and External Investigator Guide: https://www.csus.edu/compliance/research-integrity-compliance/human-subjects-research.html.

4. Classroom Research/ Research Practice

Classroom research, or research practice, is an activity required for a course grade with no intent of publishing or presenting results at an off-campus conference or symposium. The IRB does not require the review of student classroom research.

5. Research Not Involving Human Subjects

Although an activity may be considered research, it may not involve human subjects. Persons involved in a research activity are not considered to be human subjects when the following apply:

- The information collected is not *about* the individual. That is, the person interviewed/surveyed is asked to provide information specific to his/her expertise or profession as opposed to personal information about him/herself (i.e. opinions, thoughts, or perceptions). For example, a welder asked to describe the composite of shielding gas, shielding gas flow rate, and formation of the weld bead is not disclosing information about him/herself and, as such, is not a research subject. Likewise, an entomologist who describes the varieties of pesticide used to control a specific pest and to identify the types of pesticides that are used most frequently is contributing his/her expertise rather than information about him/herself.

- The person is asked to wear a device to measure something external to the person (air quality, environmental toxins, device functioning). No data are collected about the person.

- The information must be about a living individual to qualify as a human subject. Review of death records does not involve human subjects.

III. Regulatory Approval Criteria and IRB Review

Regulated research (reviewed by the Full Board or through an Expedited review) must adhere to regulatory approval criteria listed in 45 CFR 46.111. This document explains the various items that are assessed during an IRB review and how to meet regulatory and IRB approval criteria. In short, the approval criteria for regulated research are:

1. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented/waived.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, when appropriate.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence,

additional safeguards are necessary to protect the rights and welfare of these subjects.

Please note, the criteria only apply to research reviewed by the Full Board or through an Expedited review. Limited criteria may apply during Limited Exempt IRB review and the IRB may exercise the right to apply some criteria to exempt research.

IV. Risks vs. Benefits

A. Potential Benefits

The IRB uses information about anticipated benefits expected to result from the study in conjunction with potential risks associated with participation to determine whether the study should occur. Anticipated benefits may be to the subject, the population from which the subject was drawn, scientific knowledge or society. Therefore, the investigator must provide the IRB with a clear description of the anticipated benefits that will be derived from this study. Most research does not result in direct benefits to the participants.

B. Risks

Research subjects may be exposed to risks as a result of participation in a study. An investigator must provide a description in the IRB application of any risks or discomforts the subjects might encounter as a result of participation, as well as a description of provisions he/she have made to address these risks or discomforts. The Office of Human Research Protections (OHRP) has provided the following descriptions of types of risks that may be associated with research participation:

- "Physical harm is often associated with research involving medical procedures; however, it can also be related to research testing aspects of physical fitness or public health concerns. Minor pain and discomfort, as well as drug side effects or injury resulting from an invasive procedure should be considered when evaluating exposure to physical harm. The physical risk may be minor and transient; however, some procedures may result in adverse events that may be considered serious and possibly permanent.
- Psychological harm may occur when subjects are asked to disclose or think about personal feelings and/or behaviors or are involved in an experiment that involves a manipulation of the environment or deception. The subject may experience changes in awareness, thought processes and emotion as a result.
- Social or Economic harm is associated with research where sensitive information about the subject (e.g., alcohol and other drug abuse, mental illness, illegal activities, etc.) is obtained.
- A breach in the confidentiality of this information may lead to the individual being labeled in a way that could affect their reputation, insurance eligibility, or employment."

Risks identified by the Sacramento State IRB, in addition to the risks outlined above, are:

- Educational harm that results in adverse impacts to students' opportunity to learn required educational content or the assessment of educators who provide instruction.
- Coercion due to power relationships between researcher and participants

C. Assessment of Risk

The IRB will review information provided by the investigator to evaluate the type, probability, duration and severity of risk that will or may occur during research participation. The IRB will also assess whether the risks and inconveniences associated with the research are reasonable in relation to the anticipated benefits to the subjects and in relation to the knowledge that may reasonably be expected to result from this research. The risks associated with the study must be outweighed by benefits for the IRB to approve a

study.

V. Data Collection and Management

Privacy and confidentiality risks can be minimized through proper data collection and storage procedures. The best way to ensure privacy during data collection is to conduct the study in a location that is comfortable for the participant. To adequately protect confidentiality of the data once collected, minimize access to the data by anyone other than the research team. This includes transportation of the data, storage location(s), and destruction.

A. Tests, Questionnaires, and Interview Guides

Keeping in mind the methodological distinctions between qualitative and quantitative research, the IRB reviews all research instruments such as surveys, interviews or questionnaires planned for use in data collection. As such, the investigator is asked to include all interview questions and survey instruments with the completed protocol application. The investigator may submit draft versions of study instruments for review; however, the IRB must review the final instruments (quantitative study) prior to approving the use of those instruments for data collection. Investigators conducting a qualitative study, where the development of interview questions or research instruments is dependent on the unique contexts of the study, are asked to submit draft copies of the research instruments (surveys, interview protocols, probe questions etc.) for initial review and approval. Any substantive changes to the interview or probing questions must be reported to the IRB as a protocol modification so that assessment of risk associated with participation may be evaluated.

1. Coding Data for Tracking Purposes

In survey research, an investigator may wish to code data to track respondents. This may occur when the investigator wishes to link data obtained from the same respondents on different measures, contact non-respondents, or analyze information about non-respondents to describe the study sample. The IRB considers these tactics appropriate if the informed consent process informs individuals how their identity will be recorded and/or that they may be re-contacted.

If coding will be used, the IRB will review a description of the coding scheme to determine that adequate provisions have been considered regarding maintaining the confidentiality of information collected. To avoid collecting identifiable data to code surveys, such as a student ID, it is preferred that a unique code is created from a combination of numbers or letters that participants will remember and can code the data for the researcher. For example: first initial, last initial, last four digits of their student ID or phone number (mj5367). Depending on the sample size, a less basic scheme may need to be considered (i.e. last four digits of phone and last four digits of student ID (1234-5678). This method ensures the data is de-identified, that a key linking a unique ID and a name does not need to be stored, and saves the researcher time by allowing participants to code the data themselves.

If the individual's identity is linked to the code, the IRB will review how this information will be used once data collection is complete. The best way to maintain confidentiality is to store the code in a location where only the researcher has access *as well as in a separate location from the study data*. Usually, the code is stored for three years before it is destroyed. If the study population is considered vulnerable or protected, the IRB may require the code to be destroyed upon completion of the study.

B. Internet Research

Human Subjects research conducted on the internet is subject to IRB review and approval unless the research is strictly observation of publicly available sites. Sites that are only accessibly through registration, requesting access, "friending" or "following", etc. that are otherwise hidden from the general public's view are considered closed and private sites. The conduct of research should follow the same procedures as though it was a face-to-face interaction (for example, asking the moderator for permission and posting in the forum about your study and when observations will take place). The IRB will consider study procedures in place to obtain informed consent and to protect the privacy and confidentiality of the subjects participating.

The research methods commonly conducted online that would require IRB review are: surveys, questionnaires, observations in private or closed sites, creating a site and recruiting subjects to interact on the site (public or private), commenting on a public site to initiate interaction, and more. If the researcher plans on interacting or intervening with individuals on a public site, this constitutes interaction with a subject and would require IRB review, just as it would require review if the interaction were face-to-face. Informed consent from the domain host or similar, and from the online community, should be obtained.

C. Image and Voice Recording

If a study involves the use of audio or video recordings, the IRB will review where the subject's image or voice will be stored and presented. The subject should be informed about how images or recordings may be used within the consent document. Video and audio recordings are considered direct identifiers. Collection of data should be on a device that requires a password or a device that will be stored in a secure location. If the investigator would like permission to present the recorded image for purpose other than the specific research for which the subject is consenting, an addendum to the consent is used to obtain this authorization.

Audio and video recordings are normally obtained for reliability. Once the audio is transcribed, the researcher should consider whether the identifiable audio records is necessary for long-term storage if they can delete the record and maintain the de-identified transcript. Once inter-rater reliability is completed for video recordings, the researcher should consider whether the identifiable video record is necessary for long-term storage. In some cases, video is the main source of data and long-term storage is necessary, for example speech and hearing studies.

D. Record Storage and Access

In an effort to further protect subject privacy, the IRB will review where and for how long research records will be stored and who will have access to the study data (hard copy or electronic files) once data have been collected and filed. Subjects should also be made aware of where and for how long research records should be kept, therefore, this information should also be included in the consent form. The IRB will also review procedures used to dispense of research records, samples/specimens upon completion of the research activity.

Raw data, data that is required to reconstruct the study, should be de-identified by the end of the study, unless there is justification for identifiers. Data should be stored for at least three years, which protects the integrity of your research if questions arise. Any destruction of data should not take place until three years after study completion. If data will be kept indefinitely, it should be de-identified and participants should be notified in the informed consent form. If data will be used in the future for other research projects, or will be shared with other investigators, the participants must be made aware in the informed consent form.

E. Release of Test Results

Data collected for research purposes may also be relevant to the participant's physician or other professional. In some cases, it may also be appropriate to disclose test results to the participant. This may depend on the investigator's training in accurately interpreting the results of a test that has been used for research purposes and the implications of imparting this information to the subject (e.g. access to healthcare or mental health counseling services). The protocol should address the collection of data that may also have clinical relevance and describe whether this information will be disclosed to the participant and/or to a clinical professional that is chosen by the participant.

F. Transportation of Data

If data are collected at an off-site location, the protocol should include procedures to ensure that data will be transported in a manner that minimizes risks associated with the inadvertent loss or theft of data. For example, when transporting study materials by car (samples, completed surveys, video or audio recording devices etc.), materials should be removed from the car as soon as possible. If data are to be sent to an independent facility such as a laboratory or other research center for data processing, every effort should be made to strip identifiable information from the data to avoid disclosure of private information to others outside of the research team.

The Office of Research, Innovation, and Economic Develop assist with Data Transfer/Use Agreements for the receipt or providing of data to other researchers. This protects the owner's rights and the participants confidentiality.

VI. Other Common Considerations

A. Investigator Expertise

The IRB considers the investigator's experience in the area of research to be undertaken to ensure that the research will be carried out appropriately. If the investigator is a student, the IRB will review the qualifications and experience of the faculty member responsible for the research. Both faculty and student investigators must complete the human subjects training according to their status, available online: https://www.csus.edu/compliance/research-integrity-compliance/human-subjects-research.html.

B. Research Design and Methods

The IRB protocol must include adequate information about the research design for the IRB to make an informed judgment that the design will result in meaningful and valid data. If this is not the case, the research can unnecessarily expose participants to risk.

The IRB will review a description of the research design, the scientific rationale underlying the proposed research and the statistical basis for the structure of the investigation. The IRB will also review the specific aims of the research, the hypotheses to be tested, or the questions to answer, and the type of data to be gathered and tested. If the IRB determines that the experimental designs or statistical methods are inappropriate or increase participant harm, the investigator will be asked to make revisions so that review of the protocol may continue.

C. Subject Involvement

The IRB will review the tasks that subjects will be asked to complete as study participants. Specifically, the protocol should describe what subjects will do while involved and the amount of time that participation in each aspect of the study will take. The protocol should also discuss any investigational,

experimental, or special procedures that will involve the subject (medical devices, electrical equipment, etc.).

The IRB evaluates subject selection to ensure that the burdens of research participation are distributed equitably across groups of people. Additionally, information about recruitment procedures are evaluated along with procedures to protect subject privacy during the recruitment phase.

D. Study Location

The IRB will determine the appropriateness of the location and the setting where subjects will participate in research. The protocol should address any special considerations associated with recruitment or data collection at the location (e.g., identifying potential subjects, setting appropriate for obtaining informed consent, confidentiality of data and privacy concerns).

E. Contact with Potential Subjects

1. Recruitment and Screening

The IRB requires a description of how and by whom the potential subjects will be identified and recruited. If determination of eligibility is needed, investigators should first consider gathering data directly from the subjects to determine eligibility. This method of screening does not require prior informed consent as they are not yet enrolled in the study.

If records need to be accessed to identify potential subjects, informed consent can be waived for the screening phase when the IRB feels it may be appropriate. However, other laws may apply. For example, accessing school records to determine eligibility may require a FERPA waiver or prior consent; accessing medical records to determine eligibility may require HIPAA waiver. In most cases, the investigator can ask a few questions about the individual to gain the information needed, and would not require access to someone's full record.

The IRB does not usually endorse the release of information about an individual in cases where the individual may normally consider the information to be private regardless of whether or not this information is protected by law or the ethics of a specific profession. This is most common in the snowball method wherein one participant provides contact information to another potential participant.

The IRB recommends procedures that allow for an organization or an enrolled subject to provide information about the study to a prospective subject (flyer, postcard or other announcement) that allows for the prospective subject to initiate contact if he/she would like additional information about the study.

2. Advertisement/Announcements/Flyers/Scripts

Advertising a research study for the purpose of recruiting participants is part of the informed consent process. Printed or electronic media intended for use in subject recruitment are reviewed by the IRB to ensure that the procedures proposed for informing potential subjects are not coercive and do not state or imply an outcome or other benefit beyond what is outlined in the consent documents and the protocol. Researchers cannot promise certain outcomes from the research.

Recruitment advertisements, such as flyers, postcards, brochures, newspaper advertisements, press releases, or postings on the Internet are reviewed for the accuracy and presentation of information the prospective subject needs to determine their eligibility and interest. This includes the review of content, language, and design. Information should not be misleading to subjects, as such, the use of words that

appear neutral as opposed to sensational are encouraged. Attention should be paid to the use of appropriate graphics, font size and format/design, and to accurate spelling and punctuation. The following information should be included in recruitment materials:

1. Name and contact information of the principal investigator and/or research facility;
2. Brief description of the study purpose;
3. A description of the task(s) a subject will be asked to complete
4. Eligibility criteria for subject participation;
5. Time or other commitment required of the subjects; and
6. Location of the research and person to contact for further information.

Please note: In clinical studies, advertisement materials should make no claims, either explicitly or implicitly, that the research activity is safe, effective, equivalent, or superior to any other current practice.

3. Finder's Fees and Bonus Payments

Any remuneration (in cash or in kind) for patient referral is considered unethical and is not permitted as it may compromise the provider-patient relationship. The policy set forth by the American Medical Association Code of Ethics states: "Payment by or to a physician solely for the referral of a patient is fee splitting and is unethical." Referral incentives may include, but are not limited to monetary compensation, stock options, material goods or other incentives such as food or entertainment. In addition, bonus payments to the investigator, study coordinator or provider for the purpose of encouraging recruitment of subjects to the study may compromise the judgment of the research team and is not acceptable.

The IRB does not endorse practices that involve remuneration of any kind to a provider for patient referrals or bonus payments to members of the research team for purposes of subject recruitment.

Asking students to recruit participants in exchange for extra credit is similar to finder's fees. Regardless of alternative credit options, this type of recruitment is not endorsed by the IRB.

F. Compensation and Incentives

To assist in subject recruitment, an incentive may be offered. The IRB considers the appropriateness of study compensation/incentives when reviewing protocols. The incentive should be reasonable compared to the burden or inconvenience incurred by study participants. It is important that the incentive be awarded for participation in the study rather than for completing a specific task. The purpose of the incentive is to encourage participation. By awarding the incentive only when a task is completed, it may create an undue influence that does not allow for the participant to discontinue if uncomfortable. The amount and type of incentive should not coerce or unduly influence the prospective subject into participating. In some cases, receipt of the incentive should not be contingent on study completion. Potential participants should understand what incentives will be offered before agreeing to participate in the study. The terms of the incentive should be described during the consent process and within the consent form. Incentives may also be described on recruitment materials, but should not be sensationalized or exaggerated.

Voluntary participation is achieved when the possibility of coercion or undue influence is minimized. An incentive payment or compensation for participation may compromise a person's ability to volunteer. The IRB reviews the type and amount of incentive offered to determine if it is appropriate given the potential for risk or significant discomfort that research participants may experience. There are other situations that also present the potential for coercion or undue influence that the IRB will evaluate to enhance the likelihood that the person is able to volunteer and not feel pressured to participate in the research. The recruitment and consent process are also reviewed to ensure that participants are freely volunteering to

participate in the study.

1. *Extra Credit*

Many faculty are willing to provide extra credit to students who participate in research on campus. This allows the researcher to provide an incentive and the student to experience participating in research while obtaining course credit for their time. Researchers must verify in the IRB application that faculty will provide other extra credit options to eliminate coercion. Without alternative options for extra credit, students may feel required to participate in a study. The alternative options must be equal in credit and effort. For example, the extra credit alternative to participating in a 15 minute research survey cannot be a 10 page report.

Asking students to recruit participants in exchange for extra credit is similar to finder's fees. Regardless of alternative credit options, this type of recruitment is not endorsed by the IRB.

2. *Prorating*

Prorating allows for the subject to be paid as the study progresses and does not create the perception of a penalty for discontinuing participation. In some cases, the incentive structure involves graduated payments over the course of the study to encourage continuation without creating an undue influence for participation. The IRB may accept procedures to pay the incentive in one payment at the end of the study when there is a direct benefit to the subject and a complete data set (all sessions, all interviews, all surveys) must be acquired in order to draw any conclusions from the study.

3. *Lottery*

California law prohibits lotteries (California Penal Code section 319). If (1) a prize, (2) consideration, and (3) distribution of the prize by chance is involved, the activity is illegal. Consideration for a prize is viewed as any exchange of value. If a person is eligible to win a prize without purchase, there is no consideration and the contest is legal. In a research context, the exchange of participation in a study to be entered into a drawing may be consideration for a prize and illegal. Therefore, if an individual is asked to participate in a study and declines, they must be given equal compensation by being entered into the lottery along with those who agree to participate. The individual who declines participation should be asked if they would like to enter the lottery.

If a lottery incentive will be used, the consent form will 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 the chances for winning one of the prizes (e.g., You have a one in five chance of winning a prize in the drawing). This will allow the participant to understand their chances of receiving an incentive.

4. *Verification of Cash Incentive Receipt*

Payment verification is generally required for monetary incentives. To protect the privacy of research participants, investigators must not disclose personally identifiable data to anyone outside the research team without the written consent of the subjects or their legal representative. This information includes subject name, social security number, or other identifying information. Gift cards are recommended to circumvent reporting requirements. The sponsored programs office may need to document funds which were used to pay incentives to research participants. If the incentives total $600.00 or more for an individual in a calendar year, the name and social security number and total amount paid in the year will be needed for tax purposes.

G. Conflict of Interest

The IRB considers the investigator's financial interests and potential for conflict of interest when evaluating the protection of human subjects. If a financial interest is reported that may be associated with the research, the IRB will assess the investigator's objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. The IRB will review whether the investigator (including the investigator's spouse or dependent child) or any person affiliated with the project has any financial interest, financial relationship, governance or administrative affiliation with any entity that is providing funds for or which has rights to intellectual property resulting from this study. If a financial interest is reported, the investigator may be asked to complete and upload the Financial Interest Disclosure form to the IRB application.

If the investigator has disclosed a financial interest in the research, the consent form may include a description of the financial interest as well as how the interest has been managed to avoid the possibility of a conflict in the conduct of the research.

VII. Protected Populations in Research

Protected populations or vulnerable subjects include children, prisoners, individuals with impaired decision-making capacity, those who may be economically or educationally disadvantaged, subordinate individuals (e.g., students and employees), and any other group the IRB determines to be at risk of coercion. Additional safeguards to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence must be included within the protocol (45 CFR 46.111(b)).

Considerations for vulnerable or protected participants includes evaluating the individual's ability to volunteer or provide informed consent to research participation. There are specific federal regulations (45 CFR 46 Subparts B - D) that apply to conducting research with vulnerable populations which assures that the risks associated with participation are minimal or that the research is of direct benefit to the subjects. Special considerations will be made by the IRB in reviewing protocols that include vulnerable subjects.

A. Children and Minors

The Code of Federal Regulations 45 CFR 46.401 Subpart D - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd) describes additional protections for children involved as subjects in research. In most cases, parental consent must be obtained prior to enrolling children in a study. Children will then need to provide assent to participate. Any child who does not assent, but the parent consented, cannot enroll the child in the study.

A minor is defined by the State of California as a person who is under the age of 18 years and is not legally emancipated. It is important to note that CA law does not address non-clinical research consent. A minor is not the same as a child subject to subpart D. In some cases, it is appropriate to enroll minors in research without parental consent. Additionally, 17 year old college students should not be avoided in enrollment of minimal risk research on campus. Parents no longer have FERPA access once their student is enrolled in college. Similarly, college students can exercise their autonomy.

When creating consent forms for parents and subjects, keep in mind the age and reading level. To call a 14-17 year old high school student a "child" may be off-putting, and they may prefer "minor" or "student."

1. *Wards*

The Code of Federal Regulations (46.409(a) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.406) provides guidance for children who are wards of the state, an agency, institution or entity can be included in research if:

- The research is related to their status as wards
- 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.

B. Individuals with Impaired Decision-Making

Individuals with impaired decision-making must be able to make an informed choice to participate in the research. The protocol will include a description of how the potential subject is evaluated to determine capacity to consent along with details of the consent process used to ensure that the prospective subject understands the information presented about the study. Please see the informed consent section for more information.

C. Prisoners

The Code of Federal Regulations 45 CFR 46.401 Subpart C (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc) allows the IRB to review and approve research that includes prisoners when all of the following conditions are met:

- The study does not place the subject at more than minimal risk.
- The investigation pertains to; possible causes, effects and processes of incarceration and of criminal behavior or the investigation pertains to prisons as institutional structures or of prisoners as incarcerated individuals.
- Or, the investigation pertains to conditions that affect prisoners as a class of people (e.g., vaccine trials, research on disease that is more prevalent in prisoners than other groups and research on social and psychological problems of prisoners such as alcoholism, drug addiction and sexual assaults) or the study has the likelihood of improving the health or well-being of the prisoner.

The IRB must have a prisoner advocate as a member or as a consultant to the IRB when reviewing a study involving prisoners.

D. Women and Minorities

Federal guidelines require that NIH-funded studies incorporate a research design that is sufficient to elicit information about individuals of both sexes/genders and diverse racial and ethnic groups to examine differential effects of research procedures on such groups. For more information on this topic, please go to: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

E. College Students

The IRB tries to assess situational coercion and assist investigators to reduce the pressure that a student may experience when recruited to participate in research. The IRB encourages investigators to follow recruitment procedures intended to create the opportunity for students to participate in research while reducing the possibility of unintended coercion. For example, investigators are asked to avoid one-on-one solicitations of students by faculty, graduate assistants or other students. If research participation results in

extra credit, an equitable alternative to participation in a study as a method of obtaining course credit should be offered (e.g., summarize a journal article, attend a research lecture, and assist with data collection).

If research participation is part of the course requirement, students must give consent for the use of their assignments in research as secondary data. It may be most appropriate to obtain consent at the end of course when students can evaluate the work they've completed and whether they agree to the use of that work for research. A statement in the syllabus will allow awareness and reference throughout the semester.

Asking students to recruit participants in exchange for extra credit is similar to finder's fees. Regardless of alternative credit options, this type of recruitment is not endorsed by the IRB.

F. Employees

The IRB considers the potential for coercion or undue influence and issues of confidentiality when employees are recruited as research subjects. Investigators are asked to state how voluntary participation will be ensured if the subjects under study are recruited by the employer or the researcher is sponsored by the employer. Recruitment procedures should allow for employees to participate in the study without jeopardizing their job status, their pay or their relationship with their supervisors.

G. Participants with Undocumented Immigration Status

1. Definitions

Undocumented: An undocumented student is a foreign national who: (1) entered the United States without inspection or with fraudulent documents; or (2) entered legally as a non-immigrant but then violated the terms of his or her status and remained in the United States without authorization (as defined by the National Immigration Law Center).

AB 540: made college tuition more affordable by exempting eligible CA high school graduate to pay in-state tuition at public CA colleges and universities regardless of immigration status.

DACA: A student with undocumented status, as defined above, who was brought to the U.S. as a minor and is eligible for Executive Order Deferred Action for Childhood Arrivals. These students may also have AB 540 status as well.

Dreamer: This term identifies the movement of making academic, personal and professional success an attainable reality for undocumented students. The term also embodies all of the current policies that provide access to in-state tuition, loans, a CA driver's license, professional or occupational license, and protection from deportation.

Mixed-status families: Families that are comprised of undocumented, documented, and/or native individuals.

2. IRB Review

The risk of being identified, or having a family member identified, as an undocumented, Dreamer, or DACA individual while participating in research that identifies their documentation status carries significant potential harm for the individual beyond those ordinarily encountered in daily life. These risks include psychological, sociological, and economic harm. With appropriate protections in place, the

probability of someone being identified is mitigated. However, the consequences of identification of these participants justify requiring an **expedited or full board review by the IRB** for studies involving individuals identified as undocumented, as opposed to exempt review by a department research review committee or another third party.

3. *Recruitment*

Recruitment is a main concern and should not lead to direct identification or labeling of individuals. The Dreamer Resource Center (DRC) on campus is an excellent resource to assist investigators with subject recruitment. Alternatively, a random sample of the overall student population can also be used, as long as the specific population is not targeted through privileged information (ex: sending a recruitment email to only AB 540). The individuals should have the option of contacting the investigator directly (ex: not in reply to a recruitment e-mail) if they are interested in participating in the research, or a link to an anonymous survey can be included in the recruitment message. This is intended to protect the participants by breaking the link, for anyone other than the investigator, between receiving recruitment information and responding to the invitation. A response in a non-secure mode such as e-mail could put them at risk by identifying their status along with their e-mail address and/or name. Communication (i.e. emails, texts) with participants identifying them as undocumented, Dreamer, or DACA should be destroyed by the investigator as soon as possible once the communication is no longer needed.

4. *Informed Consent*

When obtaining consent from participants, signatures should not be collected to reduce the possibility of re-identification of research data or identification of those who participated. The last paragraph statement, "By signing this form…" should instead read to the effect of, "By verbally consenting and participating in this study…" The consent document should be left with the participant to take home, and this document will contain the investigator's and IRB's contact information in the event they wish to withdraw from the study or have questions. Templates are available on the Sacramento State IRB website.

5. *Location of Research*

Only private locations should be considered when determining where to meet with a participant if face-to-face interaction is to occur. Locations that allow others to overhear the conversation will place participants at risk of being revealed as undocumented. This may be in the participant's home, in a conference room, a group study room in the library, or a private office, as examples. Coffee shops, restaurants, and other public spaces do not provide adequate privacy and will not suffice.

6. *Data Management*

As soon as participant information is under your care for research purposes, you are charged with keeping their information private and confidential, whether or not the participant is concerned about others knowing their undocumented status. In the event your research data is subpoenaed, or your emails are subjected to a California Public Records Act request, your data must be clean of identifying information.

If contact information is collected by the investigator, the information must not be connected to the research data. A strong justification must be made for storing contact information. If this information needs to be retained, it must be stored in a locked or password protected location separate from the raw data and only accessible to the investigator. Contact information must be destroyed or deleted from all locations, e.g. a hard drive, as soon as data collection has ended. Contact information should not be stored on portable devices nor stored in a cloud-based system.

Research data must be stored in a location that only the researcher(s) have access to, keeping in mind that all raw data must be free of any direct identifiers. Paper documents should be stored in locked drawers or rooms where only the researcher has the key. Electronic data must be stored on one hard drive that only the researcher has access to. This can be a laptop that is password protected, a password protected computer, a password protected hard drive on the Sacramento State network, or a portable and password protected hard drive. Data should not be stored in a cloud-based system.

Raw data (not including contact information) should be kept for a minimum of three years to support the integrity and validity of your results. A reminder should be scheduled to destroy the data at the end of three years. This destruction does not include de-identified aggregate data or the analysis of data.

7. Reporting of Results

Results should never report identities or be so descriptive that an individual could be identified through indirect identifiers (i.e. gender, age, country of origin, school, and major all combined could lead to the identification of an individual).

VIII. Informed Consent Process

A. Purpose of Informed Consent Process and Documentation

Investigators must obtain legal informed consent from the participant or participant's legally authorized representative (LAR) **before** conducting any research procedures, unless the informed consent requirements are waived by the IRB. **Informed consent is more than just obtaining a signature on the informed consent form.** It is an ongoing process of information exchanged between the participant and investigator, or other study team member authorized to conduct the informed consent process. Informed consent involves giving the prospective participant sufficient information about the research including the risks and potential benefits to allow them to make an informed and voluntary decision regarding participation.

The consent process begins during participant recruitment and includes any oral instructions and/or explanations, the presentation of the informed consent form and any other pertinent materials approved by the IRB, the opportunity to ask questions and receive answers, and the signing of the informed consent form by the participant or LAR and the Principal Investigator. Throughout the study the investigator and other IRB approved study team members should encourage participants to ask questions at any time during procedures or study visits, or contact the investigator for any questions which arise between study visits.

Informed consent may only be sought under these circumstances:

1. Assessing the prospective research participant's capacity to consent prior to obtaining signature on the informed consent document, to ensure that s/he is able to understand study procedures and the risks and benefits of participation,
2. Providing prospective subject or LAR sufficient opportunity to discuss and consider whether or not to participate,
3. providing the participant or LAR with information that a reasonable person would want to have regarding possible participation, and opportunity to discuss,
4. Ensuring the information in the informed consent document is written and presented at approximately an 8th grade reading level and in a language that is understandable to the participant or LAR.

5. Excluding any exculpatory language from the informed consent process in which the participant is made to waive, or appear to waive, any of their legal rights, and releases or appears to release employees or agents from liability for negligence.
6. Informed consent must begin with a concise and focused presentation (written or oral) of the key information that is most likely to assist a prospective subjects or LAR in understanding the reasons why one might or might not want to participate in the research.
7. As a whole, informed consent must present sufficient detail relating to the research, and cannot be provided in lists or bullet points.
8. Ensuring participants give consent without coercion or undue influence.

The form must be signed by the participant or the participants LAR. A copy of the consent form language will be provided to the participant or the participants LAR.

Consent may be obtained electronically so long as the informed consent process meets all required elements of informed consent. Documentation (signature) can be waived.

B. Observation of the Informed Consent Process

The IRB has the authority to observe the informed consent process of any currently active research study. Situations where the IRB might consider such an observation might include reports of a complaint or possibility of undue influence or coercion. An IRB member or designee may observe a consent session as an impartial observer.

C. Informed Consent Reading Level

Federal regulations require that informed consent documentation be written at the appropriate reading level of the potential participant population and be obtained in a language that is understandable to the participant or the participant's LAR. General guidance is that the consent form be written at approximately an 8th grade reading level. Refrain from using acronyms or jargon that is discipline specific.

D. Required Elements of Informed Consent

Federal Regulations mandate the inclusion of the following fundamental informed consent basic elements and additional elements:

1. Name of the Study,
2. Name of the Investigator(s),
3. A statement that the study involves research,
4. An explanation of the purpose of the research,
5. Expected duration of the subject's participation,
6. A description of the research procedures,
7. Identification of any procedures which are experimental,
8. A description of any reasonably foreseeable risks or discomforts to the participant,
9. A description of any benefits to the participant or others which may reasonably be expected from the research,
10. Alternatives to participation which may be advantageous to the participant, if any,
11. Extent of privacy and confidentiality,
12. For studies which are greater than minimal risk: An explanation as to whether medical treatment is available if injury occurs and what they consist of or where information may be obtained,

13. An explanation of who to contact for answers to pertinent questions regarding the research, participants rights, research related injury, or to voice concern about a specific research project,
14. A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefit to which the participant is otherwise entitled,
15. If research involves the collection of identifiable private information or identifiable biospecimens, state that:
    a. Identifiers might be removed from the data or specimens and that de-identified information could be used for research studies or distributed to another investigator for future research studies without additional informed consent, or
    b. Information or biospecimens collected for the study will not be used or distributed for future research, even if identifiers are removed.

Additional Elements of Informed Consent, as appropriate:

1. A statement that a particular treatment or procedure may involve risk to the participant,
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard for the subject's consent,
3. Any additional costs that may result from participation,
4. Consequences of a participant's decision to withdraw from the study and procedures for orderly termination of participation by the subject,
5. Significant new findings: the participant must be informed of any significant new findings which may affect the risks or benefits of the research and the participants willingness to continue participation,
6. The approximate number of participants to be enrolled,
7. The amount and schedule of all payments to the participant,
8. Any real or apparent conflict of interest by the investigators,
9. For research involving biospecimens, a statement that biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit,
10. Statement regarding whether clinically relevant research results or individual results will be disclosed to the subjects and under what conditions,
11. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.

E. Deception or Incomplete Disclosure

Deception involves not fully informing subjects of the real purpose of the study or providing false information about the study to subjects. This may be appropriate and justifiable in some circumstances, particularly in social and behavioral research, but is also questionable from an ethical standpoint since informed consent is compromised. If the protocol involves deception, the IRB will review a complete description of how deception will be used. The IRB will need justification for the inclusion of deception and possible alternatives to the use of deception. In studies involving deception, the protocol should include procedures to debrief subjects following participation.

If deception in research is to be approved under exemption category 3 (45 CFR 46.104(3)) the subject must authorize the deception through the informed consent process to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Debriefing

In behavioral research involving deception, an ethical practice is to debrief subjects after their

participation. The debriefing statement should be presented both orally and in writing. Debriefing procedures should include a written statement that will be summarized and provided to subjects to read in more detail if they choose. Along with a description of the deception involved and an explanation about the true purpose of the research, include a statement to inform subjects of their right to withdraw their data from the study and still receive course credit if they feel upset or uncomfortable with the deception involved. Referral information should also be provided to the subject should participation in this study raise personal concerns that he/she would like to discuss with a clinical professional.

F. Waiver of Signature on the Informed Consent Form

The IRB may waive the requirement to obtain written documentation (signatures) of informed consent (45 CFR 46.117(c)). In the event the IRB approves a waiver of documentation of informed consent the IRB will require a written description of the information to be provided to participants, which is usually an informed consent form without a signature line. In approving the waiver, the IRB must find and document any of the following:

1. The only record linking the participant and the research would be the signed consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. In this case the participant will be asked whether s/he wants documentation linking them to the research, and the participants wishes will govern.

2. The research presents no more than minimal risk of harm to the participants and involves procedures for which written consent is not normally required outside of the research context.

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

G. Alteration of Informed Consent

Federal regulations permit the IRB to approve a consent procedure that omits some or alters some or all of the required and additional elements of informed consent. None of the items outlined in Section VIII. A. of this procedure can be omitted. To approve such a waiver or alteration, the IRB must find and document the following conditions are met:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation (e.g. debriefing)

If the research involves public benefit and service programs conducted by or subject to the approval of state or local officials:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those

programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

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

H. Parental Consent

If a child will be involved as a study participant, the IRB will review procedures used to obtain and document consent from the parent or guardian. The parental consent process, including documentation, will include all the required elements of informed consent.

The IRB may waive the requirement for parental consent if it is determined that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not required to protect the subjects (e.g. neglected or abused children). Parental consent can only be waived 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 (for example, appointing a child advocate). The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

1. Assent of Children

Children may not provide consent for participation in research. They may provide assent. The ability for a child to provide assent depends upon the child's age and maturity. Assent is demonstrated by a child's positive agreement to participate in research whether documented or not. The IRB requires that investigators make adequate provision to solicit assent from children. To this end, the IRB will review a description of the process for obtaining assent from a child participant.

If the IRB determines child participants are capable of providing assent, they will determine whether or not assent should be documented. Generally, children are able to read and write to some extent by age 7 and can provide documentation of assent. Written documentation is not required for children when:

1. A child is under the age of 7
2. It is determined that the minor is incapable of being reasonably consulted
3. The research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research

When documentation is not required, the IRB requires that the investigator conduct the assent process verbally. The PI should submit a script of the verbal assent process for IRB review and approval. Information presented to the child should be age appropriate and include an introduction and basic information about what s/he will be asked to do if they participate.

Research involving minors between the ages of 14-17 can provide their assent on the same document as parental consent, so parent and child can read and review the informed consent form together. Children younger than 13 should have a separate and simple form to sign and, if under the age of 7, should not need to provide a signature. In some instances, child assent can be waived, but is limited to certain types of research.

I. Special Considerations

1. Obtaining Consent of Non-English Speaking Persons

The investigator is responsible for working with the IRB to determine that an effective and appropriate method is in place to deliver information about the study and receive consent from the participant or LAR. This may be a translation of the informed consent form or requiring a translator be present. The investigator should either be able to communicate directly with participants or LARs or have a translator present to assist in answering questions about the informed consent form and the study.

2. Obtaining Consent from Cognitively Impaired Persons

If participants are identified as being cognitively impaired, it may be necessary to include additional procedures during the consent process to ensure that the prospective subject understands the information that is being presented about the study. This may involve adding questions at the end of each section of the consent document to use in assessing participant comprehension of the consent content. This mechanism allows for the investigator to clarify the participant's understanding of specific aspects of the study as the consent process occurs (e.g., "Do you understand what will happen during the testing phase?" "Do you know how many times you will come to the clinic?"). If the individual is not legally able to consent for him/herself, the person who is legally authorized to speak on behalf of the individual is responsible for determining whether the proposed study is appropriate.

3. Internet Research

The consent information should explain added risks associated with privacy violations and strategies developed to reduce the risk of privacy loss or breach of confidentiality. If IP addresses will be tracked, this should be disclosed with the justification (to ensure one response or to remind those who have not participated yet). Normally documentation of consent is waived for internet research and only requires the participant be presented with the information and click through to the research.

G. Exempt Research and Informed Consent

The IRB requires informed consent of exempt research unless an appropriate justification is provided. Since exempt research is minimal risk, several of the basic elements and additional elements of informed consent do not need to be included and most often a signature will not be required. Simple surveys can provide consent language as a cover page or statement prior to the survey.

When audio or video recordings will be used in exempt research, direct identifiers are already being collected and informed consent should be documented with signatures.

Deception
If deception in research is to be approved under exemption category 3 (45 CFR 46.104(3)) the subject must authorize the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Children
Exempt research involving children does not have to meet federal requirements in Subpart D for parental consent and child assent. It is usual for the IRB to require child assent and parental consent, however, some situations may allow for minors to provide their own consent or assent or may allow for alternative informed consent procedures as follows:

1. Minors in college should only participate in research that was approved as exempt, or expedited research that has received IRB approval to include minors.
2. Exempt category 1 and 2 research can apply for an "opt-out" informed consent procedure. Child assent cannot be waived.

The IRB will make the final determination as to what is plausible and reasonable for the researcher to obtain regarding parental consent and child assent.

IX. Certificate of Confidentiality

If the research includes disclosure of potentially sensitive or illegal information, additional measures to protect the participant's privacy and confidentiality may be needed. A federal Certificate of Confidentiality provides additional protection for the subject in that the data would be protected from subpoena by a court of law. To initiate the process to obtain a Certificate of Confidentiality for this study, contact:

Olga Boikess, National Institute of Mental Health, 6001 Executive Boulevard, Room 8253, MSC 9653, Bethesda, MD 20892-9653, Email: oboikess@mail.nih.gov . Upon receipt of the Certificate, forward a copy to the IRB. Visit the NIH Office of Extramural Research website at http://grants1.nih.gov/grants/policy/coc/ for more information.

X. Compliance with other Federal, State, and Local Laws

The principal investigator will follow and adhere to all applicable state and local laws in jurisdictions where research is taking place.

A. Mandated reporting

State law and mandated reporting requirements may limit the extent to which the investigator is able to protect the subject's confidentiality. If through interview or measurement, the subject is *likely* to disclose illegal or dangerous behavior (e.g., if the subject reports any kind of abuse or serious harm to self or others) the investigator may be required by law to disclose whether and to whom information will be reported. The investigator must include a description of the limits to confidentiality within the consent document.

B. FERPA

The Family Educational Rights and Privacy Act (FERPA) is a federal privacy law that gives parents and/or students certain protections with regard to their children's/their education records, such as report cards, transcripts, disciplinary records, contact and family information, and class schedules. This law means that any investigator intending to obtain non-directory information for research purposes that do not fall within the exceptions must first obtain written consent from the parent/guardian or the college student. More information can be found here:
https://www2.ed.gov/policy/gen/guid/fpco/brochures/parents.html

C. HIPAA

The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. HIPAA rules do not apply to health related information provided to the researcher directly from the subject through interaction. Research is defined in the Privacy Rule as, "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." See 45 CFR 164.501. A

covered entity may always use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions outlined on this page: https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html

D. CA Lottery

Please see Lottery for information.

E. CA Education Code

The IRB will require prospective parental consent in the following situation:

California Education Code 51513 "No test, questionnaire, survey, or examination containing any questions about the pupil's personal beliefs or practices in sex, family life, morality, and religion, or any questions about the pupil's parents' or guardians' beliefs and practices in sex, family life, morality, and religion, shall be administered to any pupil in kindergarten or grades 1 to 12, inclusive, unless the parent or guardian of the pupil is notified in writing that this test, questionnaire, survey, or examination is to be administered and the parent or guardian of the pupil gives written permission for the pupil to take this test, questionnaire, survey, or examination."

F. Tribal Law

Many tribes throughout the United States have their own requirements for research conduct involving members of their tribe. Some tribes have their own IRBs. Consultation with a tribe prior to recruitment must be conducted and a letter of support or other form of support from a tribal leader must be provided in the IRB application.

G. PPRA

The Federal Protection of Pupil Rights Amendment (PPRA) – Identifies eight protected areas that governs the proper notification and administration of surveys or evaluations funded by the Department of Education in K-12 settings. Parents must opt-out if they do not want their child to take such surveys (rights transfer to the student once they attend college or reach the age of 18). More information can be found here: http://familypolicy.ed.gov/content/ppra-requirements.

XI. IRB Submission and Review

For all information regarding IRB, please view our website: https://www.csus.edu/compliance/research-integrity-compliance/human-subjects-research.html.