INSTITUTIONAL REVIEW BOARD
POLICIES AND PROCEDURES

Office of Research and Sponsored Projects

Acknowledgments

This document was developed in part by San Diego State University's human subjects program. We acknowledge their commitment to the protection of human subjects in research and thank them for their generous offer in allowing us to use their template in creating procedures for California State University, Fullerton's Institutional Review Board.

Preface

This document was developed to enhance the protection of human participants in research conducted under the auspices of California State University, Fullerton (CSUF), Resources for content included the Code of Federal Regulations (45 CFR 46), The Belmont Report, The OHRP IRB Guidebook and CSUF's University Policy Statement (620.000).

Table of Contents

Chapter 1 Institutional Review Board (IRB) General Information

Institutional Responsibility

Institutions receiving U.S. Department of Health and Human Services (DHHS) funds to conduct research with human participants must assume responsibility for the protection of the rights and welfare of human subjects in compliance with federal regulations. Each institution is required to document this information within a Federal-wide Assurance issued by the U.S. Department of Health and Human Services Office of Human Research Protections. CSUF has agreed that regardless of funding source, all human subjects' protocols will be reviewed by the terms of the Federal Wide Assurance with the Office for Human Research Protections (OHRP) to ensure that all research conducted within the jurisdiction complies with the Code of Federal Regulations Part 46 (45 CFR 46) and any additional human subjects' regulations and policies of a supporting Department or Agency, if required. CSUF IRB's Assurance No. is FWA00015384.

University Administrative Support

Administrative support for California State University, Fullerton's Institutional Review Board (CSUF IRB) is provided through the Office of Research and Sponsored Projects. This office is also responsible for establishing and maintaining a program in support of ethical and responsible human subjects research conducted under the auspices of CSUF. This is accomplished through proactive oversight of approved research *(Continuing Review Program),* internet access to relevant resources, ongoing education and training, and periodic assessment of resources dedicated in support of these activities.

IRB Responsibility

The CSUF IRB implements a review process established within the Code of Federal Regulations to ensure that human subjects research complies with federal regulations, institutional policies, and ethical standards. The CSUF IRB serves to protect the rights and ensure the safety of people involved as participants in research. The CSUF IRB also assists the investigator in complying with federal and state regulations and institutional standards for human subjects research. The CSUF IRB is guided by the ethical principles as outlined in the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* also known as *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research.*

IRB and Institutional Authority

The CSUF IRB may approve research reviewed or may require that modifications to the protocol be made to secure approval to conduct the research. The CSUF IRB may also disapprove of the research. Decisions made by the CSUF IRB are communicated in writing to the investigator (45 CFR 46.109). The CSUF IRB may also suspend or terminate approval of research that is not conducted per the approved protocol or that has been associated with unexpected serious harm to subjects (45 CFR 46.113) Actions taken by the CSUF IRB to suspend or terminate approval will be documented in writing and reported to the Investigator, institutional officials and, if necessary, to the Office for Human Research Protections (OHRP).

Research that is approved by the CSUF IRB may be subject to further review by the officials of the institution. Authorized institutional officials may approve or disapprove research planned by an employee, student, or agent of CSUF. The institutional officials may not approve research involving human subjects that have not been approved by the CSUF IRB (45 CFR 46.112).

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. (45 CFR 46.102(d).)

The CSUF IRB reviews research when procedures are proposed to collect information for publication, dissemination to an outside agency, or generalized public knowledge about a living individual. The procedure to collect data can be but is not limited to: the use of a survey, interview, observation, experimentation, or the analysis of human tissues, records, samples, or other data previously collected from human subjects.

Some other instances that require CSUF IRB review occur when the institution is engaged in human subjects research.

For example:

Institution employees or agents in connection with his/her institutional responsibilities, intervene or interact with human subjects for purposes of research or obtain individually identifiable private information about human subjects for purposes of research; or

The institution receives a direct federal award to conduct human subject research, even where all activities involving human participants are carried out by a subcontractor or collaborator.

Research that involves the use of the institution's non-public information to identify or contact human research participants or prospective participants or utilizes any institutional property or facilities in connection with human subjects research.

Chapter 2 IRB Membership

IRB Composition

The President of CSUF appoints the CSUF IRB members per federal requirements (45 CFR 46.107). The CSUF IRB is composed of members representing the University faculty, staff, and local community. Membership includes at least one individual whose primary concerns are in the nonscientific areas and at least one member not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution. The faculty members represent a variety of disciplines representative of the research reviewed. In addition to federal policy, the CSUF IRB composition may also include a student representative and directors (or their designated representative) from each of the following departments: Student Health and Counseling. Environmental Health & Safety; Grants & Contracts. (UPS 620.000)

Selection/Appointments

The CSUF IRB Chair or the Regulatory Compliance Coordinator will confirm that CSUF IRB membership complies with regulations (46.107). If an additional member(s) is needed, several methods are used to identify candidates. The existing members or the Academic Senate may be asked to provide recommendations to the Chair. Department Chairs may be contacted to suggest faculty who are available and interested. Faculty who are active in the research community may be contacted directly to discuss service to the committee. The selection of a

Vice-Chair will be appointed by the members of the CSUF IRB and the appointment term will coincide with each academic year and/or member appointment. Permanent representation of department members to the CSUF IRB will be made by the Academic Senate. The Chair and/or the Regulatory Compliance Coordinator will forward recommendations to the President. Vacancies occurring during an academic year shall be filled as soon as possible (UPS 620.000).

Alternate Member

An alternate member may be appointed to the CSUF IRB to serve in the absence of a member. The alternate is selected based on the expertise and perspective they can bring to the review process. Due to the diversity in an individual's academic and/or professional training as well as experience, an alternate member is selected to represent an absent member (if needed) using the following criteria: scientist/MD., scientist/non-M.D.; nonscientist, or community member (45 CFR 46.107).

Chapter 3 IRB Member Responsibilities

Member Training

CSUF IRB members participate in initial and continuing education by reviewing relevant materials on issues, regulations, and guidance concerning human subjects' protections (45 CFR 46). Successful completion of the CITI Program training module(s) is a mechanism for the CSUF research community, including CSUF IRB members, to demonstrate a basic understanding of both federal and CSUF - specific ethical principles and regulatory compliance practices. In addition to the CITI Program training modules, CSUF IRB members are familiar with the following:

- Institutional Review Board Guidebook. https://www.hhs.gov/ohrp/education-and-outreach/archived-materials/index.html
- Code of Federal Regulations (45 CFR 46) https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML
- The Belmont Report *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*
- Office for Human Research Protections - Policy and Guidance (https://www.hhs.gov/ohrp/regulations-and-policy/index.html).

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

The CSUF IRB membership includes those familiar with the type of research routinely conducted in the social and behavioral sciences. The CSUF IRB recognizes that its members must be sufficiently qualified through experience and expertise. Including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, it also recognizes that additional expertise may be necessary when reviewing a protocol that involves a vulnerable category of subjects (45 CFR 46.107). The IRB may request a consultation from an individual with competence in a specific area when issues relevant to a protocol require expertise above or beyond that available on the CSUF IRB. Individuals invited to comment due to their expertise may not vote on a motion.

Departmental Review Process

Four University units including Health and Human Development, Kinesiology and Health Science, Psychology, and Sociology have a "permanent" member on the CSUF IRB as appointed by the Academic Senate each academic year. These units are entitled to a Departmental Review Process that allows the CSUF IRB member to review and comment on proposals at the exempt and expedited levels before review by the CSUF IRB. The Department Review Process does not Issue IRB approval but rather the CSUF IRB will take into consideration the department members' comments. Any research involving more than minimal risk is not eligible for department review and must be reviewed by the full committee.

Primary Reviewer Process

The primary reviewer is responsible for presenting an in-depth review of all protocol documents submitted to the CSUF IRB members during the scheduled meeting and identifies areas of the research that require elaboration before securing approval. A committee member is identified in part as a primary reviewer based on his or her expertise in the discipline in which the research is taking place as long as he or she does not have a conflicting interest in the study.

A primary reviewer is used for full committee review and designated on the meeting agenda. This process is used for initial and continuing review as well as significant proposed protocol modifications, which require review by the full committee.

The primary reviewer reviews the entire application packet including the protocol, consent documents, grant application (if applicable), recruitment materials, and other supporting documents (study instruments. letters of support, etc.)

For continuing review conducted during a convened meeting, the primary reviewer receives a request for continuation of approval along with the consent form(s) and a progress report provided by the Principle Investigator. The continuation of approval request includes the number of subjects intended for study, the number of subjects accrued, a summary of any significant adverse events or unexpected problems, a summary of protocol revisions approved by the IRB since the last Full Committee review, current literature that may influence the conduct of the study and an update of financial Interests (if applicable). A copy of the current consent form should also be provided when asking for continuing review. The primary reviewer may also have access to the original protocol documents before the convened meeting. Materials describing proposed protocol modifications are accessible to the primary reviewer as a standard practice.

Full Committee Review Requirements

Each CSUF IRB member receives notification before a convened from the IRB Office a protocol has been assigned to a Full-Review meeting. Full-Review protocol applications for initial submission, modification requests, and/or renewal requests will include the consent documents, recruitment materials, and other supporting documents (study instruments, letters of support, etc.) and the investigator's brochure or the grant proposal if applicable. The protocols are accessible through the online Cayuse IRB system.

Subcommittee Procedures

A subcommittee of the CSUF IRB is defined as one or more experienced CSUF IRB members designated by the CSUF IRB Chair or Regulatory Compliance Coordinator to act on behalf of the committee when action by the full board is not required (45 CFR 46.110). The CSUF IRB can vote at meetings to have a protocol further reviewed by a subcommittee contingent upon issuing approval.

Review of Significant Adverse Events (SAE)

In the event of a Significant Adverse Event (SAE), the Investigator should report immediately but no later than five (5) days following the SAE the following information to the CSUF IRB. Upon receipt of the SAE report, the Chair of the CSUF IRB or Regulatory Compliance Coordinate will review, comment and/or determine if further action or information from the investigator may be required. At the discretion of the CSUF IRB Chair (or designee as appointed by the Chair), a convened meeting of the CSUF IRB may be called for review and further action or recommendation to the investigator regarding the SAE.

Enforcement

The CSUF IRB shall report to the Associate Vice President for Academic Affairs on any projects that fail to protect the rights of participants and may recommend project suspension or termination. The Office of the Vice President for Academic Affairs shall be responsible for enforcement of the recommendations of the CSUF IRB. Any researcher demonstrating persistent or serious disregard of the CSUF IRB, including especially any serious harm to human participants resulting from disregard of the CSUF IRB shall be subject to disciplinary action.

The CSUF IRB, Regulatory Compliance Coordinator, the study sponsor, and other state or federal regulatory entities may have access to any data records being conducted as research sponsored by CSUF for compliance monitoring purposes. These same parties shall have the authority to observe or have a third party observe the consent process and the research. (UPS 620.000).

Quorum and Voting Requirements (46.107 and 46.108)

To convene a meeting of the CSUF IRB, a majority of the voting members must be present. The committee may not convene without a member whose primary concerns are nonscientific. If the quorum falls during the meeting (early departures, loss of nonscientist, excused for conflict) the meeting will be terminated until the quorum can be restored. Any action taken without a quorum present is considered invalid.

An alternate member may be assigned to replace a member who is not able to attend the convened meeting. The alternate may vote only when in attendance to replace a voting member. Individuals designated as non-voting members may contribute to the discussion; however, may not serve as a primary reviewer, propose a motion, or vote on a motion. For a motion to pass, it must receive the approval of a majority of voting members present at the meeting.

IRB Member Conflict of Interest

Regulations stipulate that an IRB member may not participate in the initial or continuing review of a project in which the member has a conflicting interest except in response to the information requested by the committee (45 CFR 46.107e). If a member has a conflict of interest (personal, professional, or financial), he/she will leave the meeting room while discussion and voting occur. This will be documented on the review documents as well as in the meeting minutes. If the quorum should fall due to the absence of the member in conflict, the CSUF IRB Chair will determine whether the member may remain present and abstain from the vote to retain the quorum.

Education Requirement

CSUF IRB requires all researchers who submit an IRB application for review and approval to successfully complete the Collaborative Institutional Training Initiative (CITI Program) *Social and Behavioral for Research Investigators* module. This requirement is designed to encourage an understanding of values toward responsible conduct in research. The tutorial covers basic ethical principles and practices to apply whenever human subjects are involved in research studies. The content is based on the Code of Federal Regulations that pertain to human subjects (45 CFR 46), Ethical Principles and Guidelines for the Protection of Human Subjects - known as The Belmont Report, and CSUF's Federal-wide Assurance. By completing the assessment portion of the tutorial, the investigator demonstrates the knowledge of human subjects' protections necessary to satisfy this requirement.

Chapter 4 IRB Investigator / Faculty Advisor

Investigator Responsibility

Protecting the rights and welfare of the research subject is a shared responsibility of the IRB and the investigator. Ultimately, the investigator is responsible for the conduct of the study. This includes the application and monitoring of ethical practices, compliance with state/federal regulations and institutional practices, and supervision/training of research staff. Individuals conducting research under the auspices of CSUF are required to comply with all federal, state, and institutional regulations and policies regulations for the protection of human research subjects.

Faculty Advisor's Responsibility – Supervising Student Research

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

Ensure that the student has reviewed and understands the federal regulations that govern research involving human subjects, the Belmont Report, and the CSUF IRB's Federal-wide Assurance before developing a study that involves human subjects.

Review the student's online application submission before it is certified and submitted to the IRB for further review.

Meet with the student investigator to monitor the study progress.

Be available to the student investigator to supervise and address problems should they arise.

Oversee the prompt reporting of any adverse events.

Arrange for an alternate faculty sponsor to assume these duties when unavailable (vacation or sabbatical).

Monitor the research activity to ensure that the protocol approved by the IRB is followed.

Students will verify that their faculty advisor will comply with the stated responsibilities during the online application process.

Chapter 5 When Review Is Required?

Definitions

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

Research

The Department of Health and Human Services (DHHS) Code of Federal Regulations (45 CFR 46,102d) has defined research as, "A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." As described in the Belmont Report, "...the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).

Human Subject

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

Generalizable Knowledge

The IRB considers generalizable knowledge to include the dissemination of research findings beyond the boundaries of the institution (e.g., publication (Including thesis or dissertation) or presentation or use outside the specific instructional setting. The exception to the parameters defined occurs when a report of findings is issued to an agency that has contracted with the university to acquire programmatic information (e.g., needs assessment. program evaluation, quality control).

For more human subjects research-related definitions, please visit the Office for Human Research Protections (OHRP) website: (LINK) http://ohro.osoohs.dhhs.gov/lrb/lrb alossary.htm.

When is IRB Review Required?

CSUF IRB review is required when the institution is engaged in human subject research. This occurs when an agent or employee of the institution collects data that is for publication or generalized public knowledge and includes but is not limited to the following:

Intervenes with a living individual for research purposes (e.g., to draw/collect blood or other biological samples, dispense drugs, administer treatments, use physical sensors, test sensory acuity, collect Information by survey, interview oral history).

Manipulates an individual's environment for research purposes (control environmental light. sound, temperature, and social interactions).

Interacts with an individual for research purposes (obtain consent, conduct interviews, screen potential subjects). Please note: Employees who make information available about a study and/or obtain permission from an individual to release contact information to an investigator but do not consent individuals nor act on behalf of the investigator are not engaged in research.

Releases individually identifiable private information or allows an investigator to obtain an individual's private information without the individual's written consent (release of patient's name to investigators for recruitment, allowing access to an individual's academic or medical record).

Obtains, receives, or possesses private Information that is individually Identifiable (with or without a coding system) for research purposes.

Obtains, receives, or possesses individually identifiable private information for use in maintaining a statistical center for a multi-site research program.

Receives a direct HHS award to conduct human subjects research that will be carried out by a subcontractor or collaborator.

Institutional Sponsored Research

Regardless of where the research activity will occur, the CSUF IRB is required to review all research involving human subjects that are sponsored by the institution or its ancillaries.

Institutional Involvement

All research projects that involve human subjects conducted by or under the direction of any employee, student, or agent of CSUF in connection with his or her institutional responsibilities or that utilize any property or facility of this institution, whether funded or not funded, are subject to the federal regulations governing such research (see 45 CFR 46 and The Belmont Report) and to the policies and procedures outlined in CSUF's Federal Assurance.

Collaborative Research

Research conducted in collaboration with other universities, research institutions, or hospitals must be reviewed and approved by the CSUF IRB when the research is conducted by or under the direction of a CSUF employee, student or agent. Studies in which the duties of the principal investigator are formally contracted to a non-institutional performance site must obtain approval

from an IRB designated for that institution in addition to review requirements imposed by the institution's IRB.

Consultant

CSUF IRB is required to review all research conducted by or under the direction of an agent of CSUF unless the researcher is hired on his/her own time, does not utilize the institution's resources, and will not reference the institution in documents or publications associated with any reported outcomes.

Research in Foreign Countries

Research conducted in a foreign country by or under the direction of a researcher affiliated with CSUF must be approved by the CSUF IRB and adhere to University and federal/state guidelines. The standards for ethical conduct in research must be incorporated into the research design. Any proposed variations to ethical practices endorsed by CSUF and federal regulations (recruitment procedures, consent process, confidentiality practices) that result from cultural, political, or social issues unique to the country in which the research will occur must be supported by the investigator within the protocol submitted for review. An Institutional Review Board familiar with the locale in which the research will be conducted may also be required to conduct a review and provide approval. Investigators should be prepared to provide consent documents in both the native language of participants and English.

Pilot Studies

Pilot studies that meet the above-referenced definition of research that involve human subjects must receive CSUF IRB review and approval before initiation. Pilot or feasibility studies may include as few as one person who must adhere to the same federal, state, and institutional requirements to protect human subjects in research regardless of the number of subjects involved.

Secondary or Existing Data Analysis

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, must be reviewed by the CSUF IRB. It is likely that this type of research will meet the criteria for exemption and can be verified through an administrative review (45 CFR 46.101). Please note: All data included in the request to analyze existing data must exist at the time the research is proposed. This category does not apply to the prospective collection of materials.

Nonaffiliated Investigator

Persons not affiliated with CSUF that plan to conduct research that involves the use of CSUF institutional facilities and/or students must provide their institution's IRB approval to the requesting department within which they wish to obtain clearance before conducting the study. At the request of any CSUF department or faculty, the CSUF IRB may also review the study to

ensure ethical practices are implemented when conducting the research. A CSUF IRB approval notice does not replace any departmental or additional approvals which may be required between the investigator and the respective department(s).

Access of the Institution's Non-public Information

Research that involves the use of the institution's non-public Information to Identify or contact human research subjects or prospective subjects must be approved by the CSUF IRB in advance of initiating the research. CSUF IRB may request additional approval be verified from institutional departments as needed to honor the investigator's request for non-public Information and before issuing IRB approval.

Chapter 6 When Review May Not Be Required

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 (publication or presentation) are not subject to CSUF IRB review.

Consultation

Projects are not subject to CSUF IRB review when an employee of the institution consults on research but does not collect, receive or possess identifiable and private information about persons participating in the study.

In addition, projects are not subject to CSUF IRB review when an employee of the institution is engaged in research as a consultant through a non-institutional contract. In this case, research activities must occur outside of his/her institutional employment and he/she may not reference the institution in documents or publications associated with any reported outcomes.

Research Methods Courses/Class Assignments

The primary purpose of providing training in research methods is for the student to become more knowledgeable about the research process. Instructors may assign a project, in conjunction with the course, in which students design a study, recruit participants, collect and analyze data and report their findings in the form of a final paper. Since the intent of the project/assignment is to train students, the assignment is not considered to research as defined within the federal regulations and is not subject to CSUF IRB review. The course instructor is responsible for including information about ethical research practices and providing direct supervision of each project.

Projects conducted for this purpose should not exceed minimal risk, target special populations, or include sensitive subject matter.

If the course assignment produces results that may be of interest to the scientific community, CSUF IRB may recommend that the student replicate the study under a CSUF IRB-approved protocol. An IRB does not have the authority to approve research retrospectively. If the primary

intention of the student and faculty supervisor is to publish the data collected from the student's class project, then CSUF IRB approval is needed before the commencement of recruitment and data collection.

Research Not Involving Human Subjects

Although an activity may be considered research *(...systematic investigation designed to contribute to generalizable knowledge...).* It may not involve human subjects *(...*a *living individual* about *whom information is obtained through intervention or interaction).* 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 (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 pesticides used to control a specific pest and identifies 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). No data is collected about the person.

The information must be about a living individual to qualify as a human subject. A review of death records does not involve human subjects. However, analyses of biological specimens (blood, tissues) or nonpublic records **do** require CSUF IRB review and approval before analysis may begin.

Chapter 7 Review Process and Procedures

CSUF IRB will review research involving human subjects to assure that the protocol meets with federal, state, and institutional regulations. Activity involving human subjects (identification of prospective subjects, recruitment, etc.) may not be initiated until the study has been reviewed and approved by the CSUF IRB.

Three different procedures are used to review an application (Exempt, Expedited, and Full Committee). The appropriate review procedure is determined by the Chair of CSUF IRB and/or the Regulatory Compliance Coordinator applying federal regulations and based on how human subjects are involved in the research. The type of review is based on the risk associated with participation in the research, the study intervention/Interaction, and how informed consent is obtained and documented. A research protocol, informed consent statement, and additional supporting documents are required for all research projects submitted for review.

Initial or Administrative Review

Research that is considered a minimal risk and that meets federal criteria for an exempt or expedited review (e.g., use of existing data; some survey or interview procedures) may be eligible for review through administrative procedures (45 CFR 46.101 & 45 CFR 46 .110). The research protocol is evaluated to determine whether criteria are met to justify an exempt or expedited review. The CSUF IRB Chair and/or the Regulatory Compliance Coordinator will review and verify new protocols and recommend a further review of the protocol into one of three categories: exempt, expedited, or full committee. If a protocol is determined to be exempt, the investigator will be sent electronically the appropriate CSUF IRB Approval Notice. All nonexempt research will be reviewed by the full committee. Studies receiving an exempt or expedited review are reviewed on a first come first serve basis. Review notification is available to investigators approximately three weeks following application submission for on administrative review. If an application is determined to require full committee review, the researcher will be notified.

During the initial review process for both exempt and expedited reviews, questions may arise that require the investigator to provide additional information or clarification about the protocol before an Approval Notice can be issued. Questions developed during the initial review are communicated to the Investigator via the electronic Cayuse IRB system. The investigator is given a 90-day timeframe during which the protocol file will be held in a "pending status" and he/she may respond to the stipulations posed by the IRB reviewer(s). Upon receipt and acceptance by the CSUF IRB (s) of the investigator's response, approval to conduct the research is communicated to the investigator electronically. If the investigator does not respond to the stipulations for project approval within the 90-day time frame, the protocol is identified as inactive and the file is administratively closed. To re-establish the review process, a researcher will be asked to resubmit a new online application.

Exempt Review

It is important to keep in mind that the term "exempt" does not indicate that a *research project Is exempt from the entire IRB process. Rather, an exempt review means that the project is exempt from* a *full committee review.*

The majority of studies that involve data collection from adults using a survey or interview format are exempt unless the questions deal with a sensitive aspect of a subject's behavior such as illegal conduct, drug use, sexual behavior, or the use of alcohol. Surveys and interviews of minors are generally not considered exempt. Research involving pregnant women and/or fetuses, prisoners, or the institutionalized mentally disabled cannot be exempt.

If the subject's identity is not recorded (anonymous) and/or the interview/survey questions are considered non-sensitive, then the research will probably be exempt. If the subject's response to the questions would pose a risk to that person if disclosed, then the research would receive a full committee review rather than an exempt review.

For all research, the investigator is required to provide adequate information about the research to potential subjects so that an informed decision can be made regarding participation.

The following type of research qualifies for an exempt review (45 CFR 46.101):

1. Research conducted in established or commonly accepted educational settings. Involving normal educational practices, such as

    (i) Research on regular and special education Instructional strategies. Or

    (ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:

    (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

    (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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

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

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

5. Research and demonstration projects which are conducted by or subject to the approval of the federal department or agency heads, and which are designed to study, evaluate or otherwise examine:
    (i) public benefit or service programs,
    (ii) Procedures for obtaining benefits or services under those programs.
    (iii) Possible changes in or alternatives to those programs or procedures,
    (iv) Possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies,
    (i) If wholesome foods without additives are consumed or

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

Additional Information

Categories 2 and 3 are **not exempt** if the research deals with a controversial or sensitive aspect of a subject's behavior such as illegal conduct, drug use, sexual behavior, or the use of alcohol.

Surveys and interviews of children are **not exempt.**

Research involving pregnant women and/or fetuses, prisoners, or the institutionalized mentally disabled is **not exempt.**

Existing Data

The research may qualify for an exempt review if it involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. If these data sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects (45 CFR 46.101(b)(4)).

Expedited Review

The CSUF IRB Chair may review research that qualifies for an expedited review using criteria listed in 46.110 below. When conducting an expedited review, the Chair may appoint a designated reviewer(s) who has the authority to act on behalf of the CSUF IRB with the exception of disapproving the research. The CSUF IRB Chair and/or Regulatory Compliance Coordinator may also at their discretion recommend review by the full committee for expedited protocols. If a full committee review is requested for an expedited protocol, the investigator will be informed by the CSUF IRB that the protocol will be at a convened meeting. Before the meeting, the investigator will be allowed to submit any additional information and/or rebuttal regarding the review process.

The following types of research qualify for an expedited review (45 CFR 46.100)

(1) Clinical studies of drugs and medical devices only when conditions (a) or (b) are met.
   (a) Research on drugs for which an investigational new drug application (21 CFR Port 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part B12) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used by its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heal stick, ear stick, or venipuncture as follows:
   (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

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

(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings In a non-disfiguring manner; (b) deciduous teeth at the time of exfoliation or if routine patient core indicates a need for extraction;(c) permanent teeth if routine patient core indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base 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 before 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 by accepted prophylactic techniques; (I) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; a) 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 the 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. 45 CFR 46. l 01(b)(4). This listing refers only to research that is not exempt.)

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

(7) Research an individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication. cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be

exempt from the HHS regulations for the protection of human subjects. 45 CFR 46. 101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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

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

1. an expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB by the requirements outlined in 45 CFR 46.110.
2. Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45CFR 46.402(0).

Full Committee Review

If the research is not eligible for an exempt or expedited review the protocol must be reviewed by the full committee. Research protocols to be reviewed during the full committee review are accessible to the CSUF IRB members approximately 10 days in advance of the meeting.

Therefore, protocols submitted for Full Committee review must be received on or before the posted deadline dates, which Is usually two weeks before the scheduled Full Committee meeting. A primary reviewer is identified to present a specific protocol to other members in attendance. Following presentation and discussion, the CSUF IRB may vote but is not limited to one of the following options: 1) approve the protocol as it stands; 2) request revisions to the protocol to secure approval; 3) request that additional information is provided prior to further review by the Full Committee; or 4) disapprove the protocol. The CSUF IRB may make other recommendations not noted here.

Review Time Period

The research protocol may qualify for an administrative (exempt or expedited) review (45 CFR 46.101 & 45 CFR 46.110). Completion of this review process may take four to five weeks. If the research requires review by the Full Committee, the investigator will be notified by either telephone, standard mail, or electronic correspondence of the review decision following the monthly meeting date.

Approval Criteria

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

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

Risks to subjects are reasonable about anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

Selection of subjects is equitable.

Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

The research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.

There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, the cognitively impaired, or economically or educationally disadvantaged) additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Delay of Approval

The most common reason for delay is an incomplete application or an inadequate consent form. To avoid unnecessary delay, the IRB application instructions should be followed when writing the protocol, acquiring or assembling supporting documents, or developing a consent form.

Funded Research

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

Research Approved

If the research is approved, an Approval Notice from the CSUF IRB stating the approval date and terms of approval will be sent to the investigator via email.

Revisions Required to Secure Approval

If revisions to the research protocol are required to secure approval, the investigator will be notified and informed as to what revisions are required to obtain approval. Approval is not

granted until the CSUF IRB's request is met and the revisions have been reviewed and approved by the CSUF IRB. The investigator is provided with a 90-day time period within which the stipulated conditions must be addressed. The CSUF IRB determines, upon initial review, whether the investigator's response to stipulations will require subsequent review by the Full Committee or can be reviewed via subcommittee or the Chair of the CSUF IRB.

Insufficient Information to Complete Review

If a determination for approval cannot be made due to pertinent information missing from the protocol, the investigator is informed of information needed by the CSUF IRB to complete the review. Research activity may not commence until the investigator has provided the information and the IRB has reviewed and accepted the response.

Disapproval (45 CFR 46.109)

If the research is disapproved, the investigator may not conduct the proposed research. The CSUF IRB will provide the investigator with the reason for its decision. The investigator may resubmit a protocol to the IRB for review if the reasons given for disapproval can be corrected and addressed.

Approval Period (45 CFR 46.109(c))

CSUF IRB approval is valid for up to one year (364 days) from the date of initial review (45 CFR 46.109). The length and terms of approval are determined by the CSUF IRB based on project complexity, degree or type of risk associated with participation, and the investigator's history of compliance with ethical practices.

Determining Risk

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

Appeal of IRB Decision

If the investigator is not satisfied with the decision of the CSUF IRB following review, or with the process by which a decision is rendered, an appeal process may be enacted. To initiate the appeal of a CSUF IRB decision, the investigator must submit a statement to the CSUF IRB noting areas of contention. If the issue is not resolved by the Chair or through the CSUF IRB, the appeal will be forwarded to the Assistant Vice President of Research and Sponsored Projects.

Chapter 8 Protocol Development

Where to Begin?

This section provides guidance that may be useful in preparing a protocol and informed consent document for review by the IRB.

Before developing a protocol, researchers should review *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* also known as The Belmont Report, and complete the CSUF IRB required training for human ethics. The required training is the CITI Programs Social & Behavioral for Research Investigators course.

Protocol Guidance

CSUF IRB reviews the study protocol to determine study benefit and to assess risk and risk management procedures. This guidance is for use in creating a protocol specific to the research study. The protocols Project Description and Methods section of the online application is the most important section of the IRB application as it outlines the specific procedures that will be followed during the study. One of the most common reasons for delay in IRB approval is due to an incomplete protocol. Please do not assume that members of the committee understand the proposed research well enough to infer details about the study- be explicit, yet concise about the study details according to the guidance provided within each section of the online application.

Description of Project

CSUF IRB will study the categories outlined on the IRB application to gain a general understanding of the scope of the research and to verify the type of review that is needed (e.g. exempt, expedited, or Full Committee). An investigator should provide a basic understanding of why the study is being conducted, how it will be carried out, how the results will be interpreted and how risks will be managed. A brief description of purpose and signification, methods, subjects, planned analyses, and potential benefits. Potential risks, and risk management procedures should be addressed.

Statement of Purpose and Background

One of the major responsibilities of the CSUF IRB is to assess the risks and benefits of the proposed research. Part of the process of risk/benefit analysis includes reviewing what has been done in the past and what should be done in the future to gain a better understanding of the phenomenon under study. Therefore, CSUF IRB should receive adequate information and other background information as needed to justify approval of the proposed human subjects research study.

Subjects

An IRB is required to evaluate whether subject selection procedures for a given research study are fair to ensure that the burdens of research participation are distributed equitably across groups of people. Therefore, information regarding the characteristics of subjects that will be

involved in the proposed study is needed to conduct an adequate review. Additionally, CSUF IRB must consider recruitment procedures for the proposed study to ensure that a broad cross-section of research subjects are included in the research and to evaluate the procedures that will be established to protect subject privacy during the recruitment phase.

Subject Characteristics

The investigator should define the group of subjects that are appropriate for use in the research study and provide a description of subject characteristics (e.g. type of population, number of subjects, gender, age range, etc.) The investigator should provide additional information to justify the inclusion of special populations in the research where the ability to acquire informed consent may be limited. If a particular group or category of individuals is excluded from the protocol, the investigator should be prepared to provide a clear, compelling rationale and justification as to why certain individuals or classes of individuals are not selected or excluded from participation.

Number of Subjects

The investigator should state how many subjects are planned for recruitment into the study and describe how the number of subjects was determined.

Special Populations or Vulnerable Subjects

Special populations or vulnerable subjects include children, pregnant women, prisoners, physically or cognitively challenged, economic or socially disadvantaged, subordinate individuals (e.g. students and employees), and fetuses. Additional safeguards for all subjects that are likely to be vulnerable to coercion or undue influence must be included in the study to protect the rights and welfare of these subjects (45 CFR 46. l 11(7)(b)). The investigator should specify additional safeguards are included to protect these participants.

The degree to which these potential subjects are vulnerable is directly related to the degree to which these individuals are capable of volunteering or providing informed consent to research participation. There are specific federal regulations (45 CFR 46 Subparts B - D) that apply to conducting research with vulnerable populations 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.

Children

The Code of Federal Regulations (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 years and is not legally emancipated (link to California Minor Emancipation).

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

The research does not involve more than minimal risk (I.e., does not expose the child to greater risk than encountered in daily life).

The research involves greater than minimal risk, however, the individual subject may receive direct benefit from participating in the research.

The research involves greater than minimal risk with no prospect of direct benefit to the participant, however, the results of the research will contribute to generalizable knowledge about the subject's disorder or condition.

The research. while otherwise not approvable presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Involving Children in Research at School

An IRB must determine if it is appropriate to involve school children in a research study. School children can be involved in research when the data collected will be used to assess classroom instructional strategies/techniques, and curricula development. or classroom management techniques. The investigator will discuss whether class time is used or if children are participating outside of structured class time (address nonparticipating students, supervision of non-participants, procedures used to pull out children/subjects during class time, etc.).

Fetuses, Pregnant Women, and Human In Vitro Fertilization

The Code of Federal Regulations (45 CFR 46.401 Subpart B - http://ohrp.osophs.dhhs.gav/humansubjects/guidance/45cfr46.htm#subpartb) provides additional safeguards for research that involves fetuses, pregnant women, and human in vitro fertilization. Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies. Including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the Informed consent provisions of subpart A of this part;

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

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

(g) For children as defined in Sec. 46.402(0) who are pregnant. assent and permission are obtained in accord with the provisions of subpart D of this part;

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

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

(j) individuals engaged in the research will have no part in determining the viability of a neonate. The IRB must determine that all aspects of the research comply with this subpart. The IRB must give special consideration to subject selection, monitoring, and oversight of informed consent, and monitoring the research as needed. For more guidance on research Involving fetuses and human in vitro fertilization please review the Office for Human Research Protections (OHRP) IRB Guidebook: http://ohro.osophs.dhhs.gov/irb/lrb chopter6.htrn#g2. For more information on the inclusion of pregnant women in research, please go to: http://ohrp.osophs.dhhs.gov/lrb/lrb_chopter6.htrn#g3.

Cognitively Impaired (45 CFR 46.111(b))

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

Prisoners (45 CFR 46.401 Subpart C)

The Code of Federal Regulations 45 CFR 46.401 Subpart C (http://ohrp.osophs.dhhs.gov/humasubjects/guidance/45cfr46.htm#subpartc) allows an IRB to review and approve research that includes prisoners when the following conditions are met: The study does not place the subject at more than minimal risk and the investigation pertains to possible causes, effects and processes of incarceration and 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 a 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.

College Students

CSUF IRB tries to estimate the degree of situational coercion and, through guidelines, assists researchers to reduce the pressure that a student may experience when recruited to participate in research. CSUF 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, an investigator is encouraged to avoid one-on-one solicitations of students by faculty, graduate assistants, or other students. If research participation is a course requirement, offer an equitable alternative to participation in a study as a method of obtaining course credit (e.g. summarize a journal article, attend a research lecture, and assist with data collection) and conduct data collection outside of the scheduled class time.

When student records are needed to identify potential participants, the protocol must comply with the Family Educational Rights and Privacy Act (FERPA).

Employees

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

Selection Criteria & Screening

CSUF IRB will review the criteria by which subjects will be selected for study participation to determine whether subject selection practices are equitable and justified. The research protocol should also include a rationale to support the selection criteria. For the CSUF IRB to know that subjects will be selected appropriately, the protocol should describe how the inclusion/exclusion criteria will be assessed and by whom (include a description of the assessor's professional qualifications/credentials if relevant). If a particular group or category of individuals is excluded from the protocol, the investigator should be prepared to provide a clear, compelling rationale and justification as to why certain individuals or classes of individuals are not selected or excluded from participation.

CSUF IRB is concerned with protecting subject confidentiality and for ensuring that a prospective participant has been given informed consent before disclosing private information. In certain cases, investigators are interested in screening individuals before they are formally

enrolled in the study to determine whether they meet the basic study selection criteria. This process can often lead to the disclosure of private information before obtaining and documenting informed consent.

Therefore, if a screening procedure will be used, CSUF IRB requires information about how screening will take place (e.g. interview, survey, records review) and how data collected during screening will be handled if the person is found to be ineligible (e.g. used as research data or destroyed). If individuals will disclose private information, the CSUF IRB will review the procedures used to obtain consent from the person in advance of implementing screening procedures. If the protocol identifies specific inclusion and exclusion requirements to determine subject eligibility (e.g. age, physical or psychological condition), the CSUF IRB will review a screening checklist in which specific inclusion and exclusion criteria are listed and defined. Additionally, CSUF IRB will review the procedures used to document the appropriate screening of subjects.

Recruitment Source

CSUF IRB will review information regarding the location from which subjects will be recruited (e.g. schools, university campuses, fitness facilities, hospitals). CSUF IRB may request review confirmation that the investigator has obtained permission from the institution to conduct this protocol within a private facility. A Letter of Support signed by the appropriate administrator on official letterhead will need to be uploaded to the online Cayuse IRB application. The CSUF IRB will not accept email correspondence in lieu of a signed Letter of Support.

Recruitment Methods

CSUF IRB will require a description of how and by whom potential subjects will be identified and recruited. If records are accessed to identify potential subjects, CSUF IRB will review a description of procedures used to ensure that records are only accessed by those with consent from the individual.

Established Legal/Ethical Protections

The CSUF IRB will advise against the release of identifiable private information from a source to an unaffiliated researcher without the permission of the potential participant where legal and ethical guidelines prohibit the source from doing so.

An example of when this may occur is when a researcher is attempting to identify prospective participants according to specific eligibility criteria for recruitment to a study by accessing private files through a hospital or medical clinic.

To obtain permission to access private and identifiable information about a prospective subject, the researcher will need to propose procedures to obtain consent from the individuals involved. This may be in the form of a release form used by the source to document permission to release Information to the researcher (HIPM and FERPA regulations may pertain). The consent statement should include information about what information is requested, how it will be used and to whom it will be given. Review and acceptance of this consent document by the CSUF IRB are required in advance of its use.

No Established Legal/Ethical Protections

CSUF IRB recommends against the release of information about an individual where the individual about whom information is to be released may normally consider the information to be private - although not protected by law or the ethics of a specific profession.

The CSUF IRB will also advise against procedures that involve a person or organization providing information about another individual/potential subject without his/her permission for recruitment.

The CSUF 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.

Please note: Research that involves the collection or study of existing data, documents, records, or specimens where the sources are either publicly available or recorded in a manner that subjects cannot be identified, directly or through identifiers linked to the subject may meet the criteria for exempt review.

Recruitment Announcements

Advertising a research study to recruit participants is part of the informed consent process. Printed or electronic media intended for use in subject recruitment are reviewed by the CSUF 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. A copy of any intended recruitment announcement or flyer should be included with the Initial CSUF IRB application submission.

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

1. name and address of the principal investigator and/or research facility;

2. concise description of the purpose of the research;

3. eligibility criteria for subject participation;

4. time or other commitment required of the subjects: and

5. location of the research and person to contact for further information.

Please note:

Reference to incentives offered may include that subjects will be paid but the amount of payment should not be so great that it is considered coercive in attempting to recruit subjects for participation.

Recruitment Incentives – Finder's Fees and Bonus Payments

Any remuneration (in cash or any kind) for the reviewer is not permitted. The CSUF IRB does not endorse practices that involve remuneration of any kind to a provider for referrals or bonus payments to members of the research team for purposes of subject recruitment.

Chapter 9 Informed Consent Process and Procedures

Consent Purpose

"Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of **respect for persons.** It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and **voluntarily** decide whether or not to participate. This assurance protects all parties - both the subject, whose **autonomy** is respected and the investigator, who otherwise faces legal hazards. The "proxy consent" of someone other than the subject is not the same as the subject's consent, although it may be an acceptable substitute when a subject is unable to give informed consent.".

The Office for Human Research Protections (OHRP) states that "informed consent is one of the primary requirements underpinning research with human subjects; it reflects the basic principle of respect for persons." Informed consent is the knowing consent of an individual or his/her legally authorized representative, which is obtained without undue inducement or element of force or coercion. Obtaining informed consent does not end with a signature on a piece of paper. It Is a process in which the subject receives enough information about a study to decide on participation in the research. The subject should have up-to-date information about the requirements of the study during all phases of participation. The process involves reading, understanding, and signing an informed consent document as well as discussing the details of study participants with a knowledgeable member of the research team.

Informed Consent Process

The investigator is responsible for ensuring that the consent process, as specified below, is followed. Approval for the study will be withdrawn if informed consent is not obtained and properly documented.

CSUF IRB will review the process used to present the study to potential subjects. The study should be presented in a language that is clear and understandable to ensure full disclosure of the research and assess the potential subject's understanding of the research (i.e., the purpose of the study, risks, benefits, confidentiality, investigator's telephone number to call for questions, etc.).

The CSUF IRB will also consider how and where the research will be introduced to the subject to assess whether the timing and setting of the informed consent process are conducive to

objective decision-making. During the consent process, the investigator must ensure that everything is done to enhance the prospective subjects' comprehension of the information and their ability to make a choice. The CSUF IRB will review the procedures developed by the investigator that may be used to inform all research subjects of any new information that might affect their willingness to continue participating in the research. If this study involves a longitudinal design, the CSUF IRB will review a description of the mechanism whereby consent can be renegotiated, as needed, and subjects can be reminded periodically of the terms of their participation in the research.

If minor children are involved in the study, the CSUF IRB will review the process used to obtain parental consent as well as assent from the minor child.

If persons who are cognitively impaired and/or a guardian will be recruited for this study, the CSUF IRB will review information the process used to ensure that the prospective subject understands the information presented about the study.

Informed Consent Procedures

It is important to include a description of the person who will make initial contact with the potential subject to demonstrate that this individual is knowledgeable about the study, can present the information to laypeople, and will promote voluntary participation. CSUF IRB will review the qualifications and training of the individual(s) who will answer questions the subject may have about the study and document this process via a signed consent form. The investigator will identify who will verify that the consent form is signed. The CSUF IRB will review procedures developed to retain the signed copies of the consent document.

If non-English speaking persons will be recruited, CSUF IRB will require that an investigator or other person is available for translation of the consent process. An English and/or translated version of the consent form should be provided.

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

The prospective subject is given adequate information to make an informed decision about participating in the proposed study.

The nature and expectations of the research including risks and benefits are explained to the subject.

The study is presented in a language that is clear and understandable.

The subject receives answers to questions that they may have about the study.

The study is explained in an appropriate setting and with enough time conducive to good decision-making.

The prospective subject comprehends the information and can choose whether they want to participate.

The prospective subject understands that he/she retains the right to refuse or withdraw from the study at any time without penalty.

The prospective subject and/or the parent or guardian are given copies of the approved consent form(s).

Assent from Children (45 CFR 46.408)

Assent is demonstrated by a child's agreement to participate in research. In California, a child is a person who is under the age of 18 years (unless legally emancipated). It is required that the researcher makes adequate provisions to solicit assent from children unless the CSUF IRB waives this requirement. (Waivers of Assent are generally not approved by the CSUF IRB. If an investigator is requesting a waiver of the assent process, he/she must submit adequate justification to the CSUF IRB in support of the requested waiver.)

The CSUF IRB will review a description of the process and procedures for obtaining assent from the child. To determine whether the child can assent depends on the child's age and maturity, if the child is considered to be capable of providing assent, whether or not assent is documented is also determined by the IRB. Generally, children can read and write to some extent by age 7. As such, documenting assent by having the child sign an assent form is usually a procedure that is incorporated for children ages 7-17. When documentation is not required, the IRB requires that the investigator conduct the assent process through a verbal script and the IRB will review a script of what will be sold during the verbal consent process. It is also recommended that investigators avoid such language as "your mom or dad said it is okay for you to participate" since this language can be deemed coercive.

Chapter 10 Research Design and Methods

The CSUF IRB evaluates the research design to weigh the potential benefits of the study as compared to the potential risks. The protocol must include adequate information about the research design for the CSUF IRB to make an informed judgment that the design will result in meaningful and valid data. CSUF 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. CSUF IRB will also review the specific aims of the research the hypotheses to be tested, the questions to answer and the type of data to be gathered and tested.

Note that the IRB Guidelines from the Federal Government state, "The value of research depends upon the integrity of the study results. One of the ethical justifications for research involving human subjects is the social value of advancing scientific understanding and promoting human welfare by improving health care. But if a research study is so methodologically flawed that little or no reliable information will result, it Is unethical to put subjects at risk or even to inconvenience them through participation in such a study."

If the CSUF IRB determines that the experimental designs or statistical methods are inappropriate, the investigator will be asked to make revisions so that the review of the protocol may continue.

Subject Involvement

The CSUF IRB will review the tasks that subjects will be asked to complete during a study. Specifically, the protocol should describe what subjects will do during their involvement and the

amount of time that participation in each aspect of the study will take. The protocol should also discuss investigational, experimental, or special procedures that will involve the subject (medical devices, electrical equipment, etc.). If the research involves exercise testing, blood draws, or DEXA scans, review the Exercise Protocols section of this guidance.

Research Instruments

The CSUF 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 schedules and survey instruments with the completed protocol application:

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. If the protocol involves deception, CSUF IRB must review a complete description of how deception will be used. CSUF IRB will need adequate 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. In addition, the investigator should inform subjects of their right to withdraw their data from the study. If the participant should feel upset or uncomfortable with the deception involved, procedures should allow for the receipt of any incentives offered should the participant decide to discontinue participation.

Study Location

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

Special Procedures

The IRB will review a description of any investigational, experimental, or special procedures that **will** involve the subject (medical devices, electrical equipment, etc.)

Exercise Testing

If participants will be exposed to exercise or exercise-related testing, CSUF IRB will review a description of these activities. In some instances, either a short or long health history form may be required. Additional information or safeguards may need to be provided by the investigator before the CSUF IRB issuing approval.

Genetic Samples

If samples or specimens will be collected from participants and evaluated for genetic information, the investigator is required to provide the IRB with the following information:

a) If the study involves genetic testing, address issues about confidentiality of information collected.

b) State whether or not the genetic information collected about the subject could pose a risk to them (e.g. denial of health insurance because of known predisposition to illness),

c) State whether other genes will be studied in the DNA that may be shown at some point in the future to be related to illness.

d) Describe how blood samples will be coded and stored.

e) Explain whether or not any of the laboratory results will be made available to subjects, and whether the results will be added to the subject's medical record.

f) State whether the specimens collected the DNA obtained from that specimen will be used in additional research to be conducted and whether or not the DNA will have significant therapeutic or commercial value. To protect subject privacy, all information that links the subject's specimens and DNA to his/her identity must be removed before use in any research conducted outside of this specific study so that the sample provided cannot be traced back to the individual subject. **Use of Drugs and Devices**

The CSUF IRB will review a description of the drugs and/or devices proposed for use in this study and the safety and efficacy issues associated with each drug and/or device. CSUF IRB will review evidence to suggest that the product being tested is safe for use with humans.

Potential Benefits

The CSUF IRB must determine that conducting the proposed study will result in a benefit either to science/society or to the individual participant. Therefore, the investigator must provide CSUF IRB with a clear description of the anticipated benefits that will be derived from this study.

Risks

Research subjects may be exposed to risks as a result of participation in a study. When recruiting participants for research, information about the types of risks associated with study participation must be presented to each prospective subject. The Office of Human Research Protections (OHRP) has provided the following descriptions 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.

Management of Risk

The CSUF IRB will review the precautions, safeguards, and alternatives incorporated into the research activity to reduce or limit the severity, duration, and likelihood of harm. If the study activities place the subject at greater than minimal risk for injury, the investigator will describe what the potential subject will be told during the consent process and describe whether and who will cover treatment for any injury associated with the study.

Assessment of Risk

The CSUF IRB will review the information provided by the investigator to 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.

Confidentiality Procedures

To maintain the confidentiality of research data, the investigator should protect information obtained from the subject to avoid unintentional access by others. Subjects should be provided with information about the procedures used to protect the confidentiality and advised that confidentiality is provided to the extent allowed by law."

Guidelines for developing procedures to address confidentiality include:

Limit the personal information recorded to that, which is essential to the research;

Store personally identifiable data securely and limit access to the principal investigator and authorized staff;

Code data as early in the research as possible and dispose of the code linking the data to individual subjects when data has been processed;

Do not disclose personally identifiable data to anyone other than the research team without the written consent of the subjects or their legal representative. (Exceptions may be made in case of emergency need for intervention or as required by regulatory agencies).

If the data are considered to be sensitive (e.g., sexual preference or practices, use of alcohol or other drugs, illegal conduct, psychological or mental health records, etc.) and place the subject at legal risk more elaborate measures to protect confidentiality may need to be implemented. For some federally-funded research, a federal Certificate of Confidentiality may be appropriate. To apply for a federal Certificate of Confidentiality http://grants,nih.gov/grants/pollcy/coc/lndex.htm.

For more information about the purpose and use of a federal Certificate of Confidentiality, please visit the NIH Office of Extramural Research website: http://grantsl.nih.gov/grants/policy/coc/.

Anonymity and Confidentiality

Anonymity means that the identity of the subject is never recorded or associated with the data collected. Confidentiality means maintaining privacy involves recording but concealing the subject's identity or codes linked to the individual's identity. The CSUF IRB will review the procedures used to maintain either anonymous or confidential data. If the subject's identity will be recorded or a code will be created which is linked to the subject's identity, the CSUF IRB will review the rationale for doing so. If it is necessary to track information over time, consider using a coding strategy that Is not linked to the subject's identity if possible, CSUF IRB policy is that confidentiality is maintained to the extent allowed by law").

Reportable Disclosures

State law and mandated reporting requirements may limit the extent to which the investigator can 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 must disclose whether and to whom the information will be reported. Include a description of the limits to confidentiality within the consent document (i.e., state "confidential to the extent allowed by law").

Coding Data for Tracking Purposes

In survey research, an investigator may wish to code data to track respondents. The investigator may wish to re-contact non-respondents or publish information about non-respondents to describe the study sample. CSUF IRB considers these tactics appropriate as long as individuals are informed at the beginning of the study during the informed consent process. If coding will be used for tracking purposes, CSUF IRB will review a description of the coding scheme used to track respondents and non-respondents. 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.

Image and Voice Recording

CSUF IRB will review where the subject's image or voice will be presented and to whom if the study involves the use of audio or video recordings. The subject should be informed about how images may be used within the consent document. If the investigator would like permission to present the recorded image for purposes other than the specific research for which the subject is consenting, an addendum to the consent is used to obtain this authorization.

Record Storage and Access

To further protect subject privacy, CSUF IRB will review where and for how long research records will be stored, who will have access to the study data (hard copy or electronic files, and when data will be destroyed. Once data have been collected and filed, the IRB will review procedures used to dispense research records, and samples/specimens upon completion of the research activity.

Release of Results

Data collected for research purposes may also be relevant to a third party or other professional. In some cases, it may also be appropriate to disclose data to the participant. This may depend on the investigator's training in accurately interpreting the results of a test or survey 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 relevance and describe whether this information will be disclosed to the participant and/or to a third party or another professional determined by the participant.

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.

Costs

"Participation in research may result in additional actual costs to individuals. Any anticipated costs to research participants should be described to prospective subjects during the consent process." (OHRP IRB Guidebook, Available: http://ohrp.osophs.dhhs.gov/irb/irb_chapter3.htm#e5). If this study exceeds minimal risk, state how costs about any injury incurred due to study participation will be covered and by whom. A study that exceeds minimal risk means that the probability or magnitude of harm or discomfort anticipated in the research is 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).

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. The incentive must be awarded for participation in the study rather than for completing a specific task. The purpose of the incentive is to encourage participation. The amount and type of incentive should not coerce or unduly influence the prospective subject into participating. Potential participants should understand what incentives would be offered before agreeing to participate in the study and be told under what conditions they will be entitled to receive compensation. The terms of the incentive should be described within the consent form.

Prorating

An investigator may use a prorated incentive payment system. This 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 throughout the study to encourage continuation without creating an undue influence on participation. CSUF 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 to draw any conclusions.

Coercion/Undue Influence

An IRB may approve research studies that minimize the possibility of coercion or undue influence. To do so, CSUF IRB reviews incentives to determine if they are appropriate given the potential for risk or significant discomfort that research participants may experience.

Opportunity Drawing

An opportunity drawing incentive will be used, the participant's informed consent should 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 of winning one of the prizes (e.g., *You have* a *one in five chance of winning a prize in the drawing.)*

Amount

CSUF IRB will consider the value of the incentive to determine its appropriateness and to minimize the potential for coercion.

Payment Type

The CSUF IRB will determine whether research participants are paid appropriately. If a monetary incentive will be offered, the investigator must consider how subjects will be paid - either through a gift card, cash, and/or check/money. The investigator must consider potential breaches in confidentiality if a payment type is provided in a form other than cash. Also, the participant must be aware of the exact amount and type of compensation they will be received. If it is in the form of a gift card, the participant will need to know the vendor and the dollar amount of the gift card (i.e. Starbucks gift card at $10.00). IF the participant will be receiving extra credit for their participation, they will need to know the total amount of credit they will receive (i.e. 10 extra credits).

Staggered Schedule

The investigator may want to consider compensating participants for each task in the study that is completed. A payment schedule allows for subjects to receive partial payment even if they do not complete all study activities. The amount of the incentive may change depending on the nature of the task that the participant is asked to complete. The investigator may want to consider increasing the amount of compensation each time, the subject completes a study task to promote continued study participation (for example, if the study Is longitudinal). CSUF IRB will review the payment schedule to determine that the incentive schedule is not coercive to unduly influence the subject's decision to participate.

Investigator Experience

The CSUF IRB considers the investigator's experience in the area of research to be undertaken to ensure that the research will be carried out appropriately. CSUF IRB will review a summary of the investigator's relevant research experience/training. If the investigator is a student, the IRB will also review a summary of the faculty member's experience responsible for supervising the research.

Conflict of Interest

The CSUF IRB considers the investigator's financial interests when evaluating the protection of human subjects. If a financial interest is reported, the IRB will assess the investigator's objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing, and reporting data. The Conflict of Interest committee may also review disclosures where a financial interest is reported. The IRB will review whether the investigator (including 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 must complete and attach the Financial Interest Disclosure form to the protocol.

Disclosure within Consent Form

If the investigator has disclosed a financial interest in the research, the consent form should describe 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.

Exercise Testing

Tests routinely conducted in exercise research protocols will be reviewed by the CSUF IRB to ensure that the researcher knows standardized procedures, appropriate risk management techniques are employed and that required training is received. The investigator will be required to verify compliance with the IRB-approved exercise protocol that is planned for use in a research study upon submission of the IRB application.

The exercise protocols also provide the text to include within the informed consent document. The consent text provides a description of the test procedures, associated risks, and risk management strategies that may be used by a potential subject to make an informed choice about study participation. The investigator may incorporate the content, as appropriate, within the consent document that will be used to inform the subject and document voluntary participation.

Technicians or investigators need to be knowledgeable and trained in areas regarding the administration of graded exercise tests and including the ability to conduct pre-test health screenings.

All staff should be properly trained in the application of electrodes and their respective monitoring and recording.

Internet Research

As internet research has become more and more common, guidance to assist researchers in developing research protocols in compliance with the ethical standards applied to standard survey and observational research is needed. Research conducted in the virtual world of the internet is subject to the same IRB review process and human subjects' protections as research conducted in the physical world. The main concerns of the CSUF IRB for protecting subjects involved in research on the internet are informed consent, protection of privacy, and confidentiality. These concerns pertain to survey and observational research conducted with human participants on the internet. The CSUF IRB will ask researchers to provide information as to how they will disassociate email respondents' private information to ensure confidentiality.

Survey Research

Similar guidelines to obtaining consent for exempt research apply in anonymous, internet survey research. A statement containing the following information to obtain consent for survey research conducted on the internet will be reviewed by CSUF IRB:

Describe why the study is being conducted.

State who is being recruited and why they have been chosen.

Explain what each participant will be asked to do and estimate how long it will take to complete the task.

Emphasize that participation is voluntary.

Clarify whether the participant's information will be anonymous (no identifiers, including online pseudonyms) or confidential. If confidential, indicate “to the extent allowed by law" and whether any information linked to the individual's identity (in the physical or virtual world) will be used. Researchers are encouraged to clarify their method for maintaining confidentiality (i.e. when the master list of identifiers or email addresses will be destroyed.)

Describe incentives/compensation offered or costs that may be incurred, and conditions regarding compensation (i.e. terms required for compensation, completion of the study, etc.)

Explain added risks associated with privacy violations and strategies developed to reduce the risk of privacy loss or breach of confidentiality.

Provide contact information including the name of the investigator, department phone number, and E-mail address for inquiries. Include the IRB telephone number and E-mail address for questions related to their rights as a participant in research.

Note: Confidentiality and privacy are of particular importance for internet research, given that information may be stored and accessed for indefinite periods of time. The investigator must assure the Committee that the data collected will only be accessible to the investigator.

If you are planning to collect data via the internet, efforts to enhance participant privacy and reduce risks associated with a breach of the confidentiality of subject data must be considered. Within the protocol, address the following issues as they pertain to data collection and submission procedures utilizing the internet.

Secure Data Storage. Incorporate procedures do not include the participant's name or identifiers within the database. Develop a coding scheme to protect subject privacy and confidentiality of data. Describe how/whether data will be backed-up and kept in a secure location, how long It will be stored, who will have access to the data collected, and when it will be destroyed. If not destroyed, participants should be informed that data will be kept indefinitely and it should be clarified how data will be used in the future (e.g., data collected will be used at future educational conferences, etc.)

Describe systems in place to prevent unauthorized persons (hackers) from accessing the database.

Chapter 11 Commencing Research

Modifications & New Findings

Federal regulations require that any revision to previously approved research involving human subjects receive IRB approval in advance of implementation 45 CFR 46. l 03 (b)(4)(iii)). A modification is defined by the IRB as a change that does not alter the overall character or purpose of the original project. Minor changes that do not adversely alter the overall risk-benefit profile of the study may receive an exempt or expedited review. For significant changes to protocol wherein full committee approval was issued, a full committee review may be required for approval of those proposed changes

The researcher is asked to provide a complete description of and rationale for the proposed modification and to address the effects of the modification on risks, benefits, management of risks, and informed consent. Any new findings in the literature that may influence the study procedures, risks, or benefits must also be reported to the IRB.

Changes to the consent document to inform subjects of new findings, and changes in procedures. risks and benefits to study participation must also be approved by the IRB. The CSUF IRB requests that an investigator attaches a clean copy and a highlighted copy (which shows changes) of the consent document when submitting their request. Procedures used to inform and document consent of previously enrolled subjects affected by the modification should be addressed.

Adverse Event Reporting

In the event of a Significant Adverse Event (SAE), the investigator should report immediately but no later than five (5) days following the SAE the following information to the CSUF IRB via the online Cayuse IRB system. Upon receipt of the SAE report. the Chair of the CSUF IRB or Regulatory Compliance Coordinate will review, comment and/or determine if further action or information from the investigator may be required.

At the discretion of the CSUF IRB Chair (or designee as appointed by the Chair), a convened meeting of the CSUF IRB may be called for a review and further action or recommendation to the investigator regarding the SAE.

When reporting an SAE to the CSUF IRB investigator should include but not be limited to the following Information:

1) appropriate identifying information (i.e., principal investigator's name; project title; funding agency, if applicable);

2) a complete, detailed description of the SAE and the basis for determining that it represents an unanticipated problem; and

3) a description of any actions that have been taken or proposed by the funding agency or any monitoring entity, if applicable. The investigator should also include a description of the response to the SAE (i.e., suspension of new subject enrollment, modification of protocol/informed consents, etc.)

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

Research projects must be reviewed at least annually. CSUF IRB approvals expire one year following the issuance of an approval notification. Determination for more frequent review is based on the degree of risk associated with participation and/or the involvement of subjects that require additional protections as defined by the Department of Health and Human Services.

A continuation of approval is needed if the subject recruitment and/or data collection is continuing. The investigator should request a renewal of approval before the expiration of the protocol. A Renewal Request Form should be completed along with submitting a progress report for the committee's review. Additionally, the researcher should include a copy of the current consent form. Requests for renewed approval will be reviewed in the same manner that the original approval was issued (i.e., research that was initially reviewed by the Full Committee will receive a continuing review by the Full Committee.) Request for continued approval should be submitted by the appropriate deadline dates as posted on the IRB schedule.

Renewal Notices are sent via email to the Investigator and any additional key research personnel listed on the protocol 30-60-90 days before the expiration date of the protocol. If the CSUF IRB does not receive a response to this renewal request within a 30-days of the expiration date, a termination notice will be processed, and the file will be administratively closed.

Suspension or Termination of Approval

The CSUF IRB may suspend or terminate the approval of research that is not being conducted by the requirements set forth by the committee or that has been associated with unexpected serious harm to subjects (45 CFR 46.109(0)).