INSTITUTIONAL REVIEW BOARD (IRB)

CALIFORNIA STATE UNIVERSITY, SAN BERNARDINO

Policies and Procedures for Review of Research Involving Human Participants

Introduction:

In compliance with federal regulations, California State University, San Bernardino (CSUSB) has established an Institutional Review Board (IRB) to oversee its obligations with respect to human participants. When people are involved as subjects in research or related activities conducted under university auspices, both the institution and individual researchers are responsible for assuring that the rights and welfare of participants are adequately protected. Such activities include any mode of research conducted either on or off campus. These principles have been accepted and established by the University in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46) and professional ethics (Ethical Principles in the Conduct of Research with Human Participants, American Psychological Association, 1982). The CSUSB IRB filed for a Federalwide Assurance with the Office of Human Research Protections (OHRP) as CSUSB received federal funding. Our Federawide Assurance number is FWA#

All projects involving human participants must be reviewed by the IRB **before** initiation. This applies to both faculty and student research. Activities that are routine university classroom exercises using accepted practices within a discipline do not require IRB review. This exclusion does not apply to experimental educational or training programs, or to independent study projects and thesis/project research using human participants.

Basic Principles:

a) Participation of human participants in any research project or other regulated activity (e.g, experimental demonstration, training program, interview, or questionnaire) must be voluntary.

b) Any risks to subjects must be outweighed by the sum of the benefits to subjects plus the knowledge gained by the study.

c) Informed consent to participate in a project must be obtained upon satisfactory presentation of information to potential subjects about the purposes, procedures, risks, and benefits of participation.

d) The privacy of subjects must be safeguarded by protecting **confidentiality** of information from or about subjects and/or by maintaining their **anonymity.**

Definitions:

Research: is a systematic investigation designed to develop or contribute to knowledge. This includes any mode of research, demonstration, instruction, training or related activity, survey, interview or questionnaire study. Normal university classroom activities are not subject to IRB review unless they constitute "research" as herein described.

Human subject: is a living individual about whom an investigator obtains data through intervention or interaction with the individual.

Risk: means that the possibility of physical, psychological, or sociological harm may occur as a consequence of participation in a research activity or if such participation would increase the risks beyond those encountered in ordinary, daily life.

Minimal risk: means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in the daily life of the subject or during performance of routine physical or psychological examinations or tests.

Responsibilities of Investigators:

The investigator is responsible for:

(a) obtaining IRB review and approval of any research involving human participants covered under the regulations, or registering their research with the IRE if it falls into one of the exempt categories;

(b) obtaining the legally effective informed consent of all subjects to be included in the research study, unless any or all requirements for obtaining consent have been waived by the IRE during its review;

(c) performance of the protocol as approved by the IRB; and

(d) adherence to ethical principles in the conduct of the research.

Review Board Actions:

The IRB reviews all projects involving human participants and determines whether the project should be approved, disapproved, approved with modifications, or deferred for later actions pending receipt of additional information or further clarification. Investigators are notified writing of the IRB's decision. Active research must be reviewed annually, and the researcher IS required to resubmit a new application form each year to fulfill this requirement.

Criteria for IRB Approval:

In reviewing research activities involving human participants, the IRB seeks to determine that all of the following requirements are met:

(a) Risks to subjects are minimized and reasonable. Research procedures should be consistent with sound research design, should not expose the subjects to unnecessary risk and, when possible, should be the same as those already being performed on the subjects for diagnostic purposes.

(b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects. The IRB also considers the importance of the knowledge to be gained from the research when evaluating risks vs. benefits.

(c) Selection of subjects is equitable. In making this assessment, the purposes of the research and the setting in which the research is conducted are considered. Indication of coercion or prejudice must be absent, and participation must be clearly voluntary.

(d) Informed consent is sought and documented from each prospective subject, or from the subject's legally authorized representative.

(e) Provision is made for collecting, utilizing, and storing data in a manner that protects the safety and privacy of the subjects and the confidentiality or anonymity of the data.

(f) Appropriate safeguards are included to protect the rights and welfare of the subjects. Categories of Review:

Categories of Review:

Administrative (Exempt) Review: Federal regulations provide that certain kinds of research (e.g., some surveys, field interviews, observations, evaluations of standard educational practices or tests) involving no more than minimal risk to subjects can be exempt from full IRB review and record keeping. Page 7 lists the categories for research considered exempt from review. Final determination of exempt status is the responsibility of the IRB Chair and Research Compliance Officer.

Expedited Review: Federal regulations also provide that certain kinds of research may receive expedited review. Page 8 lists the categories for research appropriate for expedited review. In such cases, only the Chair and one other member of the IRB need evaluate the proposal.

Full Board Review: For those projects that do not fit into the above two categories, a full board review by the IRB is required.

Review Procedure:

For a research proposal to receive full board or expedited review by the IRB, the investigators should fill out the online IRB application noted on the CSUSB IRB application submission website.

The online IRB application can be located on the CSUSB IRB website at https://irb.csusb.edu/applicationForms/index.html. The CSUSB IRB has moved from a hard copy IRB application submission process to an IRB online submission system called Cayuse IRB. The Cayuse IRB software provides a web-based user platform that simplifies management of your entire human subjects research portfolio with best-practice workflows that improve productivity, mitigate risk and ensure compliance. A modern, user-friendly interface guides users through the complexities of protocol completion, submission, approval and closure. Automated routing with data transparency reduces IRB review and approval times, and easy, cloud-based access is secured with ISO 27001 certified information security and data privacy. Source: https://evisions.com/products/research-administration/cayuse-irb/.

Informed Consent:

An investigator shall not involve a human subject in a research project without first having obtained the legally effective informed consent of the subject or the subject's legally authorized representative. Unless a waiver has been approved by the IRE, this informed consent must be obtained and documented in writing. Both the participant and researcher should retain a copy of the signed consent form.

Legally effective informed consent includes at least the following:

(a) identification of the researcher(s);

(b) an explanation of the nature and purpose of the research, the research method, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(c) a description of any reasonably foreseeable risks or discomfort to the subject;

(d) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(e) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(f) for research involving more than minimal risk, an explanation as to whether any compensation and/or an explanation as to whether any medical treatments is/are available if injury occurs and, if so, what they consist of or where further information may be obtained;

(g) the name of the person to contact for answers to pertinent questions about the project and the subject's rights, and who to contact in the event of a research-related injury;

(h) a statement that participation is voluntary, that refusal to participate or discontinuation of participation will involve no penalty or loss of benefits to which the subject is otherwise entitled.

Special protections are afforded minors (persons under age 18), including the need to obtain parental consent. In the case of children over seven years old, the child must also give consent. If the research is not of a sensitive nature, and little or no risks are involved, waiver of parental consent may be requested by the investigator. However, waiver of parental consent can only be granted by the IRB. These same general protections also apply to the mentally incapacitated, or other subjects who have legal guardians.

A sample consent form is given on page 6. This form is intended only as a guide. Researchers should present the required information for their particular study in the most appropriate format.

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

(a) the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. (Each subject will be asked whether he or she wants documentation linking the subject with the research and the subject's wishes will govern.)

--or--

(b) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Waiver of informed consent: Some research may be so indirect, innocuous, and innocent of imposition on the rights and welfare of human participants as to make informed consent a moot point. Therefore, any or all of the requirements for obtaining informed consent may be waived by the IRB during its review of the study. However, such action must be based upon clearly defensible grounds, and the principle investigator must include these justifications in the proposal submitted to the IRB. Specifically, waiver of informed consent may be granted if:

(a) the research involves no more than minimal risk to the subject;

(b) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (c) the research could not be practicably carried out without the waiver or alteration; and

(d) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

CATEGORIES OF RESEARCH EXEMPT (ADMINISTRATIVE)

Research activities involving human subjects that are **exempt** from IRB review are identified in 45CFR 46.101(b)(1)-(6). (Institutions and IRBs may not create new categories of exempt research under 45 CFR Part 46.) Institutions should have a clear policy in place on who shall determine what research is exempt under .46.101(b). Those persons who have authority to make a determination of what research is exempt are expected to be well-acquainted with interpretation of the regulations and the exemptions. In addition, the institution should be prepared to reinforce and review, as necessary, the method of determining what is exempt. OPRR (OHRP) advises that investigators should not have the authority to make an independent determination that research involving human subjects is exempt and should be cautioned to check with the IRB or other designated authorities concerning the status of proposed research or changes in ongoing research.

Institutions may elect to review all research under the auspices of the institution even if the research qualifies for exemption under .46.101(b). It is incumbent on the institution to advise investigators and others involved in the conduct and administration of research involving human subjects of the institutional policies for reviewing exempt research.

The CSUSB IRB has formerly adopted a policy derived from OHRP guidance of who can determine a project to be exempt. OHRP recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is exempt. Institutions should implement exemption policies that most effectively address the local setting and programs of research. OHRP recognizes that this may result in a variety of configurations of exemption authority, any of which are acceptable assuming compliance with applicable regulations.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/.

OHRP gives the institutional IRB authority in review of research with human subjects as noted in section 45 CFR 46.109, 46.112, and 46.113 of the federal regulations.

§46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a

statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.109

§46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.112

§46.113 Suspension or termination of IRB approval of research.

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

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.113.

Categories of Exempt Review:

Exempt Category 1: Educational Setting

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

- research on regular and special education instructional strategies, or
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

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Exempt Category 2: Public behavior or anonymous questionnaires

Research involving the use of:

- educational tests (cognitive, diagnostic, aptitude, achievement)
- survey procedures
- interview procedures, or
- observation of public behavior may be exempt

unless the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** 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.

Exempt Category 3: Public Officials

Research involving the use of:

- Educational tests (cognitive, diagnostic, aptitude, achievement)
- Survey procedures
- Interview procedures, or
- Observation of public behavior

Research under this category applies when research activities involve the following:

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

NOTE: This exemption does not apply to research with children except for research involving observation of public behavior where the investigator(s) do not participate in the activities being observed.

NOTE: This exemption does not apply if it involves human subjects who are elected or appointed public officials or candidates for public office or, Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exempt Category 4: Existing Data: Records Review, Pathological Specimens

- Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens may be exempt if they are being:
    - being obtained from publicly available sources **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.

NOTE: To qualify for Exemption 4, data, documents, records or specimens must already exist at the time research is proposed.

Exempt Category 5: Public Service Programs

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- public benefit or service programs
- procedures for obtaining benefits or services under those programs
- possible changes in or alternatives to those programs or procedures; **or**

- possible changes in methods or levels of payment for benefits or services under those programs.

NOTE: To qualify for Exemption 5 for Public Benefit Projects, which is for projects conducted by or subject to approval of federal agencies, the following criteria must be satisfied:

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive or nutrition services as provided under the Older Americans Act)
- The research or demonstration project must be conducted pursuant to specific federal statutory authority o There must be no statutory requirement that the project be reviewed by an IRB
- The project must not involve significant physical invasions or intrusions upon the privacy of participants
- Authorization or concurrence by funding agency

Exempt Category 6: Taste Tests

Taste and food quality evaluation and consumer acceptance studies if:

- Wholesome foods without additives are consumed; **or**
- If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE 1: This category may be applied to research involving children; however, written parental consent to include children in taste testing studies will be required.

NOTE 2: While not explicitly prohibited in the regulations, inclusion of children in Food Quality and Consumer Acceptance Studies may pose greater than minimal risk to participants and may require IRB review.

CATEGORIES OF EXPEDITED REVIEW

Applicability:

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

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

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

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

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

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

Research Categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

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

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

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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 46.101(b)(4). This listing refers only to research that is not exempt.)

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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

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

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[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 in accordance with the requirements set forth 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." 45 CFR 46.402(a).
Source: 63 FR 60364-60367, November 9, 1998.

Submitting Your Application

- Check to make sure your application is complete and submit the application through the online Cayuse IRB application submission system. Applications submitted that are incomplete will be returned.

- Any research involving children requires full board, no exception.

- Informed Consent: The informed consent document should include all 8 elements of the informed consent and be written as the proposed participants reading level and in the appropriate language. 5th and 6th grade reading level is recommended (See OHRP website for list of the 8 elements of informed consent https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html).

- Child Assent - Written at a child's language level. This informs the child, much like the informed consent but without all the elements required in an informed consent, of what research they will be asked to participate in. The assent is written at the most basic understanding level for the child and can be given to the child in writing or read orally.

- Permission Letters: Permission letters to conduct your research must be included with your IRB application. These can be uploaded in the attachments section of the Cayuse IRB application. An example would include permission letter from a principle and/or school district to conduct research at a school or within a school district sit. In some cases, only the district can provide approval to conduct research at the school site and you should contact them to ensure you attain the proper permission(s). Another example is a letter from the organization (business, public, other) where you wish to conduct your study. All letters must be on the organizations letterhead.

- You do not need to provide your thesis/dissertation information.

- **IMPORTANT NOTE 1:** *EXEMPT APPLICATIONS*: Exempt does NOT mean Exempt from filing an application for review by the Institutional Review Board of CSUSB. Exempt means Exempt from 45CFR46 of documentation of informed consent and continuing review. Only the IRB Chair, IRB Chair Designee, or the Research Compliance Officer can make the final determination your application falls under the Exempt category of research. Should your application not follow under the Exempt category you will be notified through the Cayuse IRB application submission system. If your IRB application is determined by the IRB that your application does not fall under one of the Exempt review categories you will notified through the Cayuse IRB application system to re-submit your application under Expedited or Full Board Review. For a full list of the Exempt review categories please visit the federal Office of Human Research Protections (OHRP) at the website below.
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101

- **IMPORTANT NOTE 2:** Under Expedited or Full Board Review your IRB application (protocol) is approved for 1 year and the approval period is noted on your IRB approval letter. When you approach your 1 year approval end date and have not completed your study, including recruitment, you must submit a renewal and continuing review form if you submitted your IRB application under the former hard copy submission process. The hard copy form is located under the application and forms menu on the IRB website (See the IRB website at http://irb.csusb.edu/applicationForms/index.html). If your study was approved through the Cayuse IRB application system you will be notified when your study

is coming up for renewal at 90, 60, and 30 days before the studies approval end date. The renewal and continuing review form is located in the Cayuse IRB submission system. If you fail to submit the renewal form you can no longer continue the study or enroll any new participants until the renewal is submitted and approved by the IRB.