IRB USE ONLY

HSRP #:

Date Received:

ALAMO COLLEGES DISTRICT

Palo Alto College

Human Subjects Research Protocol for Exempt, Expedited, or Full Board Review

Instructions and Researcher Certifications (Failure to follow may result in a delay in processing)

Complete this form if **"research"** will be conducted.

Do not complete this form for:
1. **non-research** activities; or
2. to **fulfill PAC coursework only** without a research activity or element.

By signing this Human Subjects Research Protocol for Exempt, Expedited, or Full Board Review (HSRP), all Principal Investigators (PIs), co-PIs, and personnel (collectively, "Researchers") certify the following:

1. CITI Training "Social & Behavioral Research - Basic/Refresher" course has been completed and is current for **any research activity** regardless of source of funding or whether unfunded (expires after three years);

2. CITI Training "Responsible Conduct of Research Course" has been completed **in addition to** the "Basic/Refresher" and is current **only if** the source of funding is the **National Institutes of Health (NIH)** or the **National Science Foundation (NSF)** (expires after three years);

3. Have read and understood the responsibilities set forth in PAC's IRB Procedures;

4. If the HSRP is submitted for a doctoral dissertation, have coordinated with the Institutional Review Board (IRB) to meet its requirements;

5. Have read and reviewed this HSRP; any applicable supporting documentation or third-party approval has been obtained from the appropriate authority and has been included as an attachment to the HSRP (e.g., recruitment script, informed consent, parental consent, child assent, school permission, facility use permission, grant/proposal, Translator Certification, Interpreter Certification, etc); have signed the HSRP electronically;

6. Will immediately report any adverse event to the Institutional Review Board (IRB)

7. Have submitted the HSRP a **minimum of thirty (30) days in advance** of the anticipated start date (additional time is required for review at full board); will communicate whether there is a **firm start date or other deadline** associated with the HSRP; and

8. Will submit a Completion Report at the conclusion of research under this HSRP.

After completing the foregoing, submit the HSRP with supporting documentation via email to
mgarcia1846@alamo.edu

For questions, email:

mgarcia1846@alamo.edu

Researchers

	Name	Email	College	Category	Category (Other)
PI					
Co-PI (1)					
Co-PI (2)					
Co-PI (3)					
Co-PI (4)					
Co-PI (5)					

Overview

A. Research Classification: (i.e., Exempt, Expedited, or Full Board Review) Other:

The IRB will ultimately be responsible for making the Research Classification and Level of Review. For guidance, see content at the end of the HSRP.

B. Anticipated Level of Review:

C. Externally funded: Award Start Date: Funding Source:

D. Title:

E. Anticipated Start Date: **F.** Estimated Completion Date:

Purpose and Objective

A. Describe the purpose of the research **in layman's terms.**

B. Describe the objective(s) and/or research questions **in layman's terms.**

Participants; Recruitment

Participants

A. Indicate whether any of the following populations will be **specifically targeted** for inclusion in the research. Each category must be answered. *Additional protections for participants may be required.*

Adults over the age of 18 (**able** to legally consent)	Yes ☐	No ☐	Prisoners (adults or minors)	Yes ☐	No ☐
Minors under the age of 18	Yes ☐	No ☐	Persons whose first language is **not** English (adults or minors)	Yes ☐	No ☐
Persons with mental disabilities (adults or minors)	Yes ☐	No ☐	Students enrolled in a researcher's course (adults or minors)	Yes ☐	No ☐
Persons with economical disadvantages (adults or minors)	Yes ☐	No ☐	Employees under the direct supervision of a researcher	Yes ☐	No ☐
Persons with educational disadvantages (adults or minors)	Yes ☐	No ☐	Persons who are sick or ill (physical or mental)	Yes ☐	No ☐
Persons with AIDS or HIV (adults or minors)	Yes ☐	No ☐	Other potentially vulnerable populations depending on the circumstances of the research (describe in "**B**")	Yes ☐	No ☐

Pregnant women, fetuses, and/or neonates Note: Research including this vulnerable population is *generally* health care/ medical studies specifically targeting research of pregnant women, fetuses, and/or neonates. Pregnant women can be included in research if all inclusion criteria is met and a specific exclusion is not part of the project design. Select "No," unless the research specifically involves the inclusion of pregnant women, fetuses, and/or neonates.	Yes ☐	No ☐			

B. Describe the criteria to determine who is included or excluded in the final participant population *(e.g., minimum age, grade range, physical characteristics, learning characteristics, professional criteria, etc)*.

C. Target number of participants *(use a minimum target if a specific target is not appropriate for the research design)*.

D. Non-PAC Participants or Facility

Complete this section **only if** the research will be conducted at a third-party facility **or** participants will be recruited from a third-party site (non-PAC).

Provide the non-PAC location or non-PAC participants to be recruited here *(include any permission as an attachment)*.

Recruitment

E(1). Method. Describe methods that will be used to identify the potential participants.

E(2). Materials. Describe how potential participants will be recruited, what materials will be used *(include as an attachment)*, and how they will be distributed *(i.e., who, what, when, where, and how)*.

E(3). Incentives. If applicable, provide the amount, type, and time of distribution of any payment/incentive to participants.

Identification of Participants; Data Collection and Storage; Equipment; Records Retention and Destruction

A. Identification of Participants. Indicate whether the data collected may contain individual identifiers (need for "confidentiality"), or whether the data will be collected anonymously.

B. Data Collection. Describe the method(s) or procedure(s) for data collection **in step-by-step, layman's terms** *(include collecting party, frequency, duration, location, etc)*. The use of audio or video recording must be justified by the research purpose/objective or future research.

C. Equipment. Describe any equipment to be used *(e.g., audio, visual)*, ownership *(e.g., PAC, personal)*, and methods of storage *(e.g., password, location)*.

D. Data Storage. Describe how the data collected will be stored, location(s), how the confidentiality of individually identifiable information will be maintained (if applicable), and who will have access. *(For audio and video recordings, address recordings and transcripts)*.

E. Records Retention and Destruction. For data collected, describe how records will be maintained, duration *(justified by research design and/or future research)*, destruction mechanism, and responsible party for each. *(Include audio and video recordings and applicable transcripts)*.

Risk to Participants; Mechanism of Protection; Outside Assistance

A. Risk to Participants. Indicate the level of risk to participants.

No risk	Yes ☐	No ☐
Minimal risk Definition: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.	Yes ☐	No ☐
Greater than minimal risk	Yes ☐	No ☐

B. Mechanism of Protection. Describe **every potential risk** to human subjects that may result from participation in the research ("Risk"), and indicate the method or procedure to be used to mitigate the potential risk ("Protection Mechanism"). Consider physical, psychological, social, legal, and economic risks *(e.g., breach of confidentiality, injury, psychological distress, pressure to conform, pressure to participate, etc)*.

	Risk	Protection Mechanism
1.		
2.		
3.		
4.		
5.		

C. Outside Assistance. If applicable, describe any outside assistance available to participants to mitigate the Risks stated above and how it will be provided *(e.g., medical care, counseling, etc)*.

Benefits to Participants; Benefits to Society

A. Benefits to Participants. If applicable, describe the potential benefits to participants as a result of taking part in the research *(exclude payments/incentives)*. If there are no benefits, then state so.

B. Benefits to Society. Describe the potential benefits to society or contribution to generalizable knowledge as a result of the research.

Waiver of Informed Consent; Waiver of Signed Informed Consent; Informed Consent Process

A(1). Is a **waiver or alteration** of informed consent requested? (i.e., entire process is waived, or basic element(s) are altered) *See Criteria for Waiver of Informed Consent at the end of the HSRP for guidance.* If **"yes,"** go to C. If **"no,"** go to A(2).	Yes ☐	No ☐	**A(2).** If **"no,"** is a waiver of **documentation of** informed consent requested? (i.e., informed consent will be obtained without participants' signatures) *See Criteria for Waiver of Documentation of Informed Consent at the end of the HSRP for guidance.* If **"yes,"** go to C. If **"no,"** go to B.	

B. Informed Consent Process. If **"no"** to both A(1) and A(2), describe below **step-by-step** how informed consent will be obtained. If the "short form" will be used, describe below *(See Informed Consent Documentation at the end of the HSRP for guidance).*

Note:

1) Participants must be given time to review the informed consent and supporting documents and ask questions.
2) For **minor participants**, researchers must obtain both parental informed consent and a separate child assent written at an appropriate reading level.
3) For participants whose **first language is not English**, informed consent may be required in English and non-English. In addition, submission of a **Translator Certification** or **Interpreter Certification** form may be required.
4) For research conducted in conjunction with **CCISD**, follow those requirements, as applicable. ORC and the IRB cannot advise on CCISD requirements.

C. Waiver of Informed Consent; Waiver of Documentation of Informed Consent. If **"yes"** to either A(1) or A(2), describe below why a waiver or alteration of informed consent **and/or** a waiver of documentation of informed consent is requested and how the applicable criteria are met based on the circumstances of the research *(see Criteria for Waiver of Informed Consent or Criteria for Waiver of Documentation of Informed Consent at the end of the HSRP for guidance)*.

Researcher Qualifications

A. Describe qualifications or attach CVs/resumes for **all personnel listed** on the HSRP.

Researcher Signatures

By signing this HSRP, the Researcher(s) certifies that he/she has read and understood the requirements and responsibilities set forth in the section entitled "Instructions and Researcher Certifications" in relation to the research. In addition, the Researcher (s) certifies that he/she will abide by any and all applicable federal, state, and/or institutional regulations, including any requirements from the Institutional Review Board (IRB).

	Name	Conflict of Interest (select one)	Date
PI			
	Signature:		
Co-PI (1)			
	Signature:		
Co-PI (2)			
	Signature:		
Co-PI (3)			
	Signature:		
Co-PI (4)			
	Signature:		
Co-PI (5)			
	Signature:		

Determination of Level of Review

Studies involving audiotaping and/or videotaping **do not qualify** for exempt review and will be reviewed at the level of expedited or full board.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Additional protections for participants may apply to research involving: pregnant women, human fetuses, and neonates; prisoners; children; and/or other vulnerable populations.

Exempt Review

(1) Research conducted in established or commonly accepted educational settings, involving normal education 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 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 the previous paragraph, 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 that are conducted by or subject to the approval of federal department or agency heads, and that are designed to study, evaluate, or otherwise examine (i.) public benefit or service programs (ii.) procedures for obtaining benefits or services under these programs (iii.) possible changes in or alternatives to those programs or procedures; or (iv.) possible changes in methods or levels of payment for benefits or services under those programs.

6) Taste and food quality evaluation and consumer acceptance studies (i.) if wholesome foods without additives are consumed or (ii.) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Review

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
- a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).
- b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

(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
(10) identified.

Criteria for Waiver of Informed Consent

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:
(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
(d) The research could not practicably be carried out without the waiver or alteration.An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:
(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Criteria for Waiver of Documentation of Informed Consent

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Informed Consent Documentation

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.