CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

View xForm - Project Application v6

This form is for new projects that have not been previously approved by CPHS.

Data entry
- Submitted 09/05/2025 3:25 PM ET by Shu-Hong Zhu, PhD

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

If personnel are not found by their email address while trying to complete the following questions, you can add them in the system with the link below. Click on the "New Contact Form" and complete it. Within a few minutes of completing the form, you will receive an email notifying you of the availability of the new contact. You should then be able to add them in the subsequent questions.

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Shu-Hong Zhu, PhD

Email: szhu@ucsd.edu **Business:** (858) 300-1056

Choose the institution with which the PI is affiliated (not the location at which the research is being conducted).

University of California, San Diego

Enter the city in which the PI's institution is located.
San Diego

Enter the state in which the PI's institution is located.

Start typing in the state name to select the name from the list.
California

Attach a copy of the PI's Curriculum Vitae.

Zhu Vita 2025 June.docx PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

Enter the Co-PI's email address by clicking on the "Add Contact" button.

If there are multiple co-principal investigators, repeat this action for all Co-PIs. If there are no Co-PIs for this project, skip this question.

No answer provided.

ADMINISTRATIVE CONTACT

Enter the email address(es) for the administrative contact(s). If you are the administrative contact, enter your email address, and enter anyone else you want listed as an administrative contact.

Shu-Hong Zhu, PhD

Email: szhu@ucsd.edu **Business:** (858) 300-1056

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

*The RO **cannot** be the same person as the PI or Co-PI. The RO must have supervisory authority, in the administrative structure of the institution, over the PI.*

Cheryl Anderson, PhD

Email: c1anderson@health.ucsd.edu **Business:** (858) 822-3699

OTHER RESEARCH STAFF

Enter the email address for any other research staff by clicking the "Add Contact" button.

Repeat this action for all other research staff not previously provided on this screen that should receive notifications about this project. If there are no additional research staff, skip this question.

Kevin Cummins, PhD
Email: kcummins@health.ucsd.edu **Business:** (858) 295-2763
Kristy Arthur, MPH, PhD
Email: kristy.arthur@cdph.ca.gov **Business:** (916) 324-4317
Catherine Hess, PhD
Email: Catherine.Hess@cdph.ca.gov **Business:** (916) 445-0944

Check for PI same as RO (internal only question) *(Internal)*

False

Project Information

SUBMITTER

Application completed by:

Shu-Hong Zhu, PhD
Email: szhu@ucsd.edu **Business:** (858) 300-1056

PREVIOUSLY APPROVED EXEMPTION

Is there a previously-approved exemption from CPHS for this project?

No

PROJECT TITLE

Enter the project title (please capitalize each word in your title).

California School-based Cannabis Survey Feasibility Study

PROJECT SITE

Indicate the primary site at which the research will be conducted.

Other

STUDY PROCEDURES

Indicate the study procedures involved in this research. Check all that apply.

Interviews
Recruitment-Participant
Surveys

TYPE OF RESEARCH REQUEST

Indicate which of the following applies to this research. Check all that apply.

*Death Data Only refers to health-related studies requesting existing mortality data from **within** the California Human Health Services Agency (CHHSA)*

*SB-13 (Information Practices Act) refers to health-related studies requesting existing data from **outside** the CHHSA (e.g. California Department of Corrections and Rehabilitation [CDCR], California Department of Education [CDE], etc.) **OR** studies requesting data **within** the CHHSA that are not state funded or involving state staff.*

Common Rule/Human Subjects refers to health-related studies that involve direct or indirect interaction with human subjects (e.g. recruitment, interviews, etc.)

*Common Rule Only refers to health-related studies requesting existing data from **within** the CHHSA (e.g. Office of Statewide Health Planning and Development [OSHPD], California Department of Public Health [CDPH], etc)*

Common rule/Human subjects

PROJECT TYPE DETAILS

Indicate which, if any, apply to this research. Check all that apply.

If the research does not involve any of following, choose "None of the above."

Minimal Risk
Consent form
Assent form
Reliance Agreement with another IRB
Informed Consent Waiver

Please click the link below to fill out the Reliance Agreement. After you've finished the form, you will need to save it locally and then attach in the space below.

Link to Authorization Agreement with Another IRB

Updated_Authorization-Agreement-with-Another-IRB-revised-3-5-2024-1-1.docx	Misc/Other

VULNERABLE POPULATIONS

Indicate which vulnerable populations, if any, will be involved with this research. Check all that apply.

If vulnerable populations are not part of the research, choose "Not applicable."
Note regarding minors: in the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted.

Minors

Please click the link below to fill out the supplement involving children. After you've finished the form, you will need to save it locally and then attach in the space below.

Link to Children Supplemental Form

Checklist-For-Research-Involving-Children_revised-2-25-22.pdf	Children Supplemental Form

Deleted Attachments: 1 (Most Recent: Checklist-For-Research-Involving-Children_revised-2-25-22.pdf on 09/05/2025 12:56 PM ET)

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
State funded

Enter name of state-funded source.
CDPH/SAPB

EXPEDITED REVIEW CONSIDERATION

Please check the criteria below that you think your project meets to qualify for an expedited review. If none of these expedited criteria are appropriate for your project, choose 'not applicable'; your protocol will be reviewed by the full committee. Note that CPHS will make the final determination of whether the project meets the criteria for expedited review.

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

***The Departments within the California Health and Human Services Agency (CHHSA) are: Aging, Alcohol and Drug Programs, Child Support Services, Community Services and Development, Developmental Services, Emergency Medical Services Authority, Health Care Services, Mental Health, Public Health, Rehabilitation, Social Services and Statewide Health Planning and Development.*

Not applicable

ANTICIPATED PROJECT START DATE

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard.

For a list of public meeting dates, see the CPHS website

10/13/2025

ANTICIPATED PROJECT END DATE

09/30/2027

Project Details

PURPOSE

Include a brief statement, less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public.

This study is being conducted to assess the feasibility of a new school-based survey of health behavior. The success of a new survey is in question because schools already feel overburdened with surveys. Reports of survey fatigue were common in our recent qualitative research on surveys in California schools. Numerous surveys are already being implemented in California schools, such as the California Healthy Kids Survey, the California Youth Tobacco Survey, and the Youth Risk Behavior Survey. However, these surveys do not provide high-quality, state-level, youth cannabis-related statistics that are representative of the State of California and its regions. The new survey would provide yearly assessments of cannabis use, risk, and protective factors. As cannabis use among youth has been increasing, state and local regulations continue to shift, and modes of administration evolve (e.g., vaping and commercial edibles), carefully measuring youths' cannabis-related behavior has become increasingly important for public health policy and practice.

The central arm of the study is designed to determine if enough schools and students would participate. To assess this, random schools throughout most of California will be selected to be invited to be surveyed. The invitation will include 1 of 4 survey packages that range in level of interaction with the school and length of the survey. Whether or not schools elect to participate is the primary outcome of the feasibility assessment. Success of a state-wide survey requires a high participation rate. Among the schools that agree to participate, surveys will be using a web-based questionnaire. It will be voluntary for students who have parental consent. Secondary goals include being able to estimate various cannabis use-related behaviors among high school students.

In addition, a new questionnaire will be tested with youth to determine if there are better ways to ask the questions. The research team will ask youth what the questions mean to them, how they went about answering the questions, and how to improve the questions. The development of good questions will help ensure the statistics from the survey will be useful to state agencies, schools, and the public.

The project will result in the development of a survey questionnaire and a report detailing the factors associated with improving the acceptability of a future survey.

MAJOR RESEARCH QUESTION

What is the major research question to be addressed in this project?

The overarching objective of the CDPH SAPB is to obtain annual, quality prevalence estimates of cannabis use among youth in California using school-based surveys. The feasibility of rolling out a large-scale survey is being assessed in the current study by measuring school-level participation and student engagement rates within the participating schools. High rates of participation and student engagement are important for obtaining quality estimates.

The primary question is: which recruitment strategies provide high rates of participation? Thus, the primary specific aim (Aim 1) is to compare the school recruitment rates when different recruitment strategies are used and when different administration packages are offered. The packages are the sets of attributes of the survey and the ancillary activities surrounding the survey at a particular school.
A secondary set of research questions asks how prevalent cannabis use is among California's high school students and in what ways and settings they are using it. Thus, the secondary aim (Aim 2) is to obtain state-wide estimates of cannabis use behavior. To achieve Aim 2, a survey questionnaire will be refined as part of the proposed protocol (Aim 2a).

Substance use behaviors and terminology are continually evolving, particularly with the recent influx of new devices (e.g., Juul, Suorin, pouches, etc.). Literature sources do not adequately capture the latest trends. Staying current and ensuring that our services remain relevant requires timely information gathered directly from the target population. Procedures addressing Aim 2a will result in the adoption or revision of the questionnaire.

Any revisions to the questionnaire will be submitted to the IRB for review. Upon IRB approval of the ultimate questionnaire, the survey will be issued to students in participating schools and prevalence estimates computed (Aim 2b).

STUDY PROCEDURES

Describe in detail all procedures for this research. Do not attach grant applications or similar documents. Information in this application must be sufficient to fully explain the procedures without such documents

Part 1: School Recruitment

Aim 1 will be addressed with a mensurative experiment (Hurlbert, 1984) where a school's response to different administration packages will be measured. In a mensurative experiment, the interaction with the system is for the sole purpose of measuring a response. This contrasts with a manipulative experiment where something is forced to change in the system, and the subsequent outcomes are then observed. Because of this distinction, mensurative experiments are often considered observational designs (Hurlbert, 1984).

The administrative packages that will be assigned to each school will vary in their attributes. In a formative study for this project (CHHS IRB# 2025-042), 12+ attributes were identified that might have an impact on schools' decisions to participate in a new survey or not. The formative study's results supported the field evaluation of the following attributes: the length of the survey, incentives, provision of staff briefings, and inclusion of survey questions specific to school and district needs. A full factorial cross between these factors would require more resources than is available; instead, four combinations of these factors were strategically selected. These packages include the Extensive Package: Full (long) survey questionnaire, incentives, debriefing and pre-briefing of staff, school-specific questions, district funding-related assessments, co-administration of local surveys, and rapidity of initial reporting of findings. The Subsample Package: Allows for a subsample of classrooms to be selected rather than the whole grade level. This package also includes prebriefing and incentives. The Key Factors Package: Allows for a short survey, incentives, and district funding-related assessments. The Minimum Package: Full (long) survey questionnaire. Details about the attributes are found in Attachment 1: Recruitment Packages & Power Analysis.

The sampling frame will include all high schools in California listed by the California Department of Education. Schools will be stratified by region and rurality. There are 11 regions in the Regional Assessment Network, including one region that corresponds to Los Angeles County. Los Angeles will be sampled using a separate sampling protocol because in recent years, UCSD has heavily recruited and sampled within the county. Many of the school districts are already partnered with our research group. Across the rest of the state, random sampling within substrata will be unbalanced and selection weighted by the student body population size. This may not provide for optimal statistical efficiency of state-wide prevalence estimates, but it will facilitate the evaluation of differences in participation rates across the state and in different settings.

Up to 40 schools can be surveyed in total for this protocol. To yield 40, school invitations might greatly exceed the target recruitment because our formative assessments suggest that recruitment rates may be low. Up to twenty new schools will be sent initial invitations each week but will be limited by the number of prior recruitments and prospects. Prospects will be defined as schools that have responded to the invitation with interest or are within two weeks of receiving their invitation or last point of contact. Bayesian optimization will be employed in each sampling iteration step to update the probabilities of which package will be assigned to each newly sampled school. This will maximize the information gain in each batch of invitations and will result in more samples being allocated to packages with the least certainty (i.e., higher estimate variance) regarding their associated recruitment rates.

Approaches to initiating and maintaining school recruitment efforts will also be compared. There will be two factors investigated, each with two treatment levels evaluated. The first factor will include the level of follow-up effort and initial point of contact. For the point of contact, either the sampled school will be contacted first or their district office will be contacted first. Getting permission from the district office is expected to reduce the perceived level of effort required by the school to accept invitations. Ensuring interest by the school allows the school to approach the district in a way that may be most advantageous to having the request processed by the most appropriate staff members at the district. The level of effort factor will include a low level that includes one email and one phone call, with no more contact until a school responds. The high level of effort includes sequential outreach to multiple leads (e.g., Principal, Vice Principal, Executive Assistant, and Socio-emotional staff lead) at the school or district until a response is issued indicating the school is or is not interested. Together with the packages, the design is a 4 X 2 X 2 factorial design. If 80 schools are selected and invited, that would result in 5 replicates per treatment combination. If response rates are low overall, up to 120 schools could get invited (~7 replicates per treatment combination). We are not expecting interactions.
Analysis: Multiple logistic regression will be used to compare recruitment among the packages and recruitment approaches. The outcome is recruitment or not and the explanatory variables are Package, Follow-up Effort, and Point of Contact. Blocking variables for region and school catchment rurality (rural or not) will also be included. Blocking variables for region and school catchment rurality (rural or not) will also be included. Power is 80% to detect an 25 percentage point difference when the underlying rate 30% for the package with the lowest recruitment rate (See Attachment 1: Recruitment Packages and Power Analysis). The multiple regression analyses will address Aim 1.
Part 2: Instrument Development

Because the proposed survey has a different focus than prior state-wide surveys, some questionnaire item development and adaptation is necessary. One of the planned steps (Aim 2a) involves the refinement of the questionnaire using cognitive testing (i.e., cognitive interviewing). This is a qualitative research methodology where participants simulate completing a

survey questionnaire but are asked to speak aloud about their thought process as they read through the questionnaire. Alternatively, they may be asked to complete the questionnaire or portions of it in silence and then be asked what they thought the questions asked and why they answered the way that they did (see Attachment 2: Cognitive Interview Guide). In some cases, participants will be asked to suggest alternative wording for the questions and response options.

Cognitive interviews will occur prior to the survey administration in schools. Cognitive interview sessions will be audio-recorded and transcribed for later review and analysis. Online interviews will be conducted over Zoom or in-person in a private interview room. Zoom recordings will be transcribed by Zoom and reviewed for accuracy by a UC San Diego research assistant (RA). In-person recordings will be made on a digital recorder and transcribed by a UC San Diego RA. Transcripts will be reviewed by the research team after each interview. Issues identified by consensus will be addressed with alterations to the question prompt. The constructs assessed will not change. Minor adjustments to the wording may be made before the next cognitive interview. Final versions of the instrument will be submitted to the IRB for approval before issuance in the school-based surveys. The questionnaire is found in Attachment 3: Pilot Instrument.

Both concurrent and retrospective probing will be used in interviews. Retrospective probing will be used as the initial approach for all participants (See Attachment 2: Cognitive Interview Guide).

Recruitment procedures are described in the Recruitment Details section.

Part 3: Student Survey

Schools opting to participate will have some flexibility in how they decide to run the survey administration. The following will outline the requirements to which schools must adhere.

Survey administration will occur in a school setting with a proctor, designated by the school and approved by the UCSD research team. Proctors must be adults affiliated with the school who hold a position in which supervision of students is part of their role. In our prior school surveys, proctors were generally teachers, substance use prevention coordinators, administrators, and counselors. Surveys will be conducted at school during normal school hours, in classrooms or other similar settings. Credentialed, or equivalent, teachers will be in the same room as students and proctors.

Survey administration will be scheduled for February-April, and at least 4 weeks after a major holiday. Individual schools and classrooms will schedule a specific date for the administration. Schools may administer throughout the day or opt to have all students take the online survey at the same time, if the size of the school does not exceed the server capacity.

Survey administration will be restricted from being issued during the first week of the semester. Teachers may not know some of their students by

name at that point, so they will be more prone to making mistakes when identifying students whose parents did not grant consent for participation. Proctors are trained to avoid asking students to openly identify themselves as someone who does not have parental consent to participate in the survey.

After conducting the survey, proctors will mail any consent forms to the UCSD project office. Proctors will be supplied with all materials necessary for returning consents to the UCSD project office, including boxes and pre-paid shipping labels sent through a service with tracking capabilities (such as FedEx or GSO).

The survey instrument is found in Attachment 3 (3.MYHBf.Pilot Instrument.doc).

Proctoring for the web-based student survey: Written instructions and video summaries will be provided to each school's designated survey coordinator regarding the process of administering the survey to students and the procedure for collecting any consent forms needed. The UCSD project manager will be available to answer questions and address problems. The manualized proctor training will cover the purpose of the study, protecting student privacy, answering student questions, facilitating student interest, and ensuring students are given both spoken and written presurvey notices. These notices are about what the survey covers, that it is voluntary, confidential, and anonymous, that respondents can skip any questions, and how to get directions for the alternative activity if a student does not wish to take the survey.

Proctors will complete a participation log at the end of each survey administration period (Attachment 4: MYHBf.ProctorForm.doc). The participation log is used to record the reasons students don't participate and any issues that arise during the administration.

Aim 2b addresses the prevalence estimates of cannabis use and associated behaviors and cognitions. Prevalence estimates will be computed using unweighted and weighted statistics based on the state-wide student sample. Estimates and their variances will be based on treating schools as the primary sampling units. Given that schools have different probabilities of being selected, this will be addressed in the weighting scheme. Because not all students at a school take the survey, in part due to differences in attendance and interest in participation, demographics will be used to further refine the weights. Finally, individual students' self-reports of recent attendance will also be included in the weights to correct for the underrepresentation of students who were absent on the days of survey administration.

Students absent on the survey administration days will be invited to complete a highly abbreviated version of the survey questionnaire. Data from these previously-absent students will be used to calibrate the weighting adjustments made for the number of days a student reported being missing. Although the abbreviated questionnaire will address only the key substance use and demographic variables, it will provide auxiliary variables to be used to improve the maximum likelihood missing value analyses that will adjust

the prevalence estimates for the missing values due to absences (Little and Rubin 2002).

Literature Cited

Chen, C. M., Slater, M.E., Castle, I-J.P., and Grant, B.F. (2016). Alcohol Use and Alcohol Use Disorders in the United States: Main Findings from the 2012–2013 National Epidemiologic Survey on Alcohol and Related Conditions-III (NESARC-III). U.S. Alcohol Epidemiologic Data Reference Manual (10). National Institutes of Health.

Hurlbert, S. H. (1984). Pseudoreplication and the design of ecological field experiments. Ecological monographs, 54(2), 187-211.

Little, R. & Rubin, D. (2002). Statistical Analysis with Missing Data. John Wiley & Sons, Inc.

Note: Attachments relevant to other sections that did not provide for documents to be uploaded are attached here.

Please upload here any tables or charts related to your study procedures and any materials (such as surveys or interview questions) that will be presented to participants.

3.MYHB.PilotInstrument.docx	Instruments
4.MYHBf.ProctorForms.docx	Instruments
9.ITLetterofAssurance.docx	Misc/Other
1.MYHBf.RecruitmentPackagesAndPowerAnalysis.docx	Protocol
2.MYHBf.CognitiveInterviewGuide.v1.docx	Questionnaires

Deleted Attachments: 8 (Most Recent: 3.MYHB.PilotInstrument.docx on 09/05/2025 1:00 PM ET)

RECORDING

Will audio or video recording occur?

Yes

Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).
Handling of the audio files will follow a weekly audited and reviewed standard operating practice. Audio files will be promptly moved from the recording device or Zoom cloud to a HIPAA-level secured internal data server, where no PID is associated with the audio file. Once the audio file has been transferred, it will be erased from the original recording device. Within two weeks, the transcripts will be amended as needed and reviewed. Only the transcriber and senior staff member reviewing transcripts will have access to the secure server's stored audio files. Once transcribed, the audio recordings will be securely erased.

DECEPTION

Will deception be used in this study?

Yes

Provide a rationale and describe the debriefing procedures.
Without asking schools to make a decision based on a limited set of administrative attributes, the evaluation of which attributes are actually critical to the schools can't be determined. In our experience administering CYTS, MyHB, and CHKS, when offered more support, schools don’t reject additional support and come to expect it. Because many of the administrative attributes are costly to provide, they will need to be determined as truly critical in order to obtain sustained funding if the survey is to be expanded to cover the whole state.

The primary and preferred mode of communication for debriefing will be real-time communication via phone/video call.

Some schools will be getting more support than initially described.

As part of the school recruitment study, some school systems will be initially offered fewer survey options and support in their survey administration package than other school systems. Immediately upon determination or notification that the school has accepted the offer to survey their students, an update to the support package will be sent to the school's main point of contact. That notification will detail the extra features or options that they will have available to them, so as to give all schools that participate access to the same baseline level of support. Schools that decline participation because of missing support features that can be made available will also be informed that they can get those features if they decide to participate.

SPECIAL NOTES:
The unit of study is the whole school system.
The debriefing script (Attachment 4) described later in this submission is attached here.

Attach the debriefing script

5.MYHBf.DebriefingScript.docx Misc/Other

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.

CDPH: Department of Public Health

Study Population

POPULATION DESCRIPTION

Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects such as: age; sex; ethnicity; and number of participants. Include requested participant number.

Part 1: Recruitment Study
The overarching purpose of this study is to evaluate the feasibility of conducting an ongoing, annual, statewide youth survey on cannabis and other substance use among California public high school students. Therefore, our sampling frame will be CDE's list of high schools.

The minimum number of schools that will be invited to participate will be 40. The adaptive design will allow for additional schools to be sampled as schools decline participation. We anticipate that the number of schools that are invited could be topped out at 160 based on research staff and timeline limitations.

There is no immediately available demographic information on the staff and leadership teams at the school districts. In addition, each school and district has different processes for arriving at a decision regarding the acceptance of an offer to survey its students. Different groups of school staff may be involved from school to school. We anticipate that in many instances, we will only be in direct contact with the initial or delegated point of contact at any given school. In other schools, we may directly interact with numerous administrators, counselors, and teachers.

Part 2: Cognitive Interviews
Six to twelve participants are expected in the cognitive interviews. A multimodal approach to recruitment will be used to ascertain a sample that will be diverse in terms of geography, gender, SES, and cultural identity. Participants will range from 18-20 years old with an intent to oversample 18-year-olds if the recruitment pool allows. Younger adults are most likely to have knowledge and perspectives that align with current high school students, as they will be in high school or have recently been of high school age.

Approximately half will be girls. Approximately half will be from Northern California. Purposive sampling will also be used to attempt to recruit informants who are each unique to the informant pool in terms of family SES, cultural identity, and urban/rural geography.

Part 3: Survey Implementation
We expect to survey up to 80,000 California high school students in grades 9-12, whose anticipated ages could range from 13-19. Students will be invited to answer a questionnaire while at school during school hours. It can range from 20 – 40 minutes. School eligibility includes being listed on the California Department of Education’s list of California high schools. Schools are excluded if they are special education only, juvenile court schools,

district/county community schools, or online only.

Student eligibility requirements include students who are enrolled at eligible schools in required grade-level courses (such as English or Social Science). We are requesting that the survey be offered in required classes, which will afford the most students the opportunity to participate and most easily sample a specific grade level. Due to limitations in staffing resources, this pilot survey will be restricted to students who speak and read English or Spanish. Both English and Spanish versions of the consent/assent and survey instruments will be available.

The target population for this phase of the study is high school students in California. There will be no limitation of involvement by sex, ethnicity, or other common demographic characteristics. Consistent with the most recent demographics available at the California Department of Education's Data Quest website, the participants will likely include approximately the same number of males and females (51% and 49%, respectively). The ethnic distribution will likely be 56% Hispanic/Latino, 20% Caucasian (non-Hispanic), 10% Asian, 5% African American, 4% American Indian, and the remaining mixed or other races.

RATIONALE

What is the rationale for studying the requested group(s) of participants?

Part 1: School Recruitment
A random sample of all schools is being used in this pilot work. If the preliminary data indicate disparities within the state occur, the full rollout will be large enough to document, evaluate, and make statistical adjustments.

Part 2: Cognitive Interviews
For formative evaluation, it is important to get a diverse set of participants to be able to build measurement instruments that are robust to the diversity of California's students. This pilot work would be followed up by a larger-scale invariance study if the survey is found to be feasible and acceptable.

Younger adults are most likely to have knowledge, perspectives, and lexicons that align with current high school students, as they will be in high school or have recently been of high school age. Recruitment of young adults is expected to provide a more representative sample than online recruiting of parent-juvenile pairs. Also, because they are more mature, developed, and not minors, they are a less vulnerable population than current high school students.

Part 3: Student Survey
The study is intended to address the prevalence of health behaviors among California high school students. A state-wide representative sample has advantages for public health practice. For this pilot study, only English and Spanish-speaking students will be eligible (17.4% of California students are English language learners, US Census). As this is a pilot, there is limited support for the development of rare languages surveys, which would exceed the coverage that is provided by currently rolled-out state-wide surveys.

RECRUITMENT DETAILS

Describe how potential subjects will be identified for recruitment. Examples include: class rosters; group membership; individuals answering an advertisement; organization position titles (e.g., presidents, web designers, etc.). How will potential participants learn about the research and how will they be recruited (e.g., flyer, email, web posting, telephone, etc.)?

Important to remember: subjects cannot be contacted before IRB approval.

Part 1 & 3: School Recruitment
The overarching purpose of this study is to evaluate the feasibility of conducting an ongoing statewide youth survey on cannabis and other substance use among California public school students. Therefore, our sampling frame will be CDE's list of high schools. From this list, schools will be randomly selected to be invited to participate. Each school will be initially contacted with a standard email and phone call that is used to initiate contact with the school. The email is short and covers the basics of the survey (See Attachment: 6 Initial School Contact). The initial phone call addresses the same information. A short initial email is important to get the attention of school staff, particularly because our initial point of contact is often not the person who has the role to consider the offer. Short initial emails are standard practice.

A more detailed email will be sent immediately upon receiving a response from the person who is identified as being the appropriate point of contact within the school or school district. This more detailed email (Attachment 7: School Recruitment and Informed Consent Emails) will outline the survey package being offered and provide notification that the school's decision is being studied. The detailed letter notifies the school that they were randomly selected, randomly assigned to an administrative package, and they can participate in the survey without participating in the recruitment study.

The level of effort used to initiate contact with the school will include a low level that includes one email and one phone call, with no more contact until the school responds. The high level of effort includes sequential outreach to multiple leads (e.g., Principal, Vice Principal, Executive Assistant, and Socio-emotional staff lead) at the school or district until a response is issued indicating the school is not interested. The high level of effort is the current standard of practice for the UCSD survey team. In many cases, the first person we have contacted at a school never acted on the original outreach or didn't forward it to the appropriate person in the institution. Follow-up communications and reaching out to multiple points of contact appears to have been necessary for some interested and willing schools to initiate the decision-making process that ultimately results in participation.

Part 2: Cognitive Interviews
Participants will be recruited from a variety of sources, including but not limited to online survey panels (such as Prolific), from leads provided

through partnerships with organizations interested in youth substance prevention, and via age and location-targeted Meta advertisements (i.e., Instagram).

Advertisements will contain the content found in the sample Instagram advertisement (Attachment 8: Social Media Ad). Prospects will be screened online and then scheduled during a real-time video call (Attachment 9: Cognitive Interview Screener and Scheduling Script). The live online screening will be conducted over a secure Zoom meeting (HIPAA Compliant) and will be used to confirm the eligibility of the prospect. Upon confirmation of eligibility and need for an informant with their substance use history and demographics, active written informed consent will be obtained prior to initiating the cognitive interview. Signed consents will be obtained electronically (DocuSign) for participants participating in an online interview. Those who participate in person at UC San Diego will need to provide physical written informed consent prior to initiating the interview. The informed consent document will be shared with the prospects at the time of scheduling and again prior to starting the interview.

Attach copies of all recruitment materials.

6.MYHB.InitialSchoolContact.docx	Recruitment Materials
7.MYHBf.SchoolRecruitmentConsentEmails.docx	Recruitment Materials
8.MYHB.ResearchAd.20250815.docx	Recruitment Materials
9.MYHBf.CogInterviewSchedulingScript.docx	Recruitment Materials

Deleted Attachments: 10 (Most Recent: 9.MYHBf.CogInterviewSchedulingScript.docx on 09/05/2025 3:18 PM ET)

SCREENING

Will subjects be screened prior to entry into the research?

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.

Part 1: School Recruitment
All High Schools that are listed by the California Department of Education will be eligible, except those that are special education only, juvenile court schools, district/county community schools, or online only. Schools where the point of contact or other members of the school refuse to be in the School Recruitment Study will be dropped from the study data, except for being tallied as a refusal. Otherwise, data about schools that do not participate in the survey will be retained and analyzed in the comparison of participating and non-participating schools.

Part 2: Cognitive Interviews
Only English or Spanish-speaking and reading persons will be eligible because these are the only languages being developed for this pilot research.

Once the instrument development is complete, the prospect, screening, and scheduling data, including personal identifying information, will be erased, unless participants give permission for their information to be retained for future research opportunities.

Part 3: Student Surveys
The population that is being served is adolescents. Their health behaviors and associated consequences can only be reasonably obtained directly from them.

The only information we will have on students who do not take the survey is from parental consent forms requesting their child not to participate. Copies of these consent forms will be collected by the proctors and returned to the study's project manager. These forms will be retained for 7 years. The total number of refusals will be tallied.

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card
Cash

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
Part 1: School Recruitment
Schools that survey all their 10th and 12th-grade classrooms will be offered Amazon credit or debit cards worth up to $500 to offset the costs of survey administration. If schools initiate the distribution of the consent forms and schedule the survey date, they will receive the full amount. This amount was developed and fielded in coordination with Southern California high schools. It reflects a low-end estimate of the costs incurred by schools for the organization and deployment of the survey. At an individual school, dozens of teachers and staff may spend over 30 minutes reviewing, preparing, and debriefing on survey-related matters. When considering opportunity costs and aggregate school staff time compensation, the compensation amount underestimates the burden to schools.

Part 2: Cognitive Interviews
Cognitive interview participants will be provided with a $25 gift card to thank them for their time and will be provided compensation for their travel if they complete an in-person interview. Anyone who starts the interview will get $15. Anyone who spends at least half the time completing the interview will receive the full amount.
Fast food minimum wage in California is $20/hour. The amount of time organizing and participating in the interview is expected to total >1.25 hours for most participants.

Part 3: Student Surveys
Students will not receive any individualized incentives. They may benefit from the information being collected at the school, resulting in changes to the school's programming and resources. Some schools may provide classrooms with high student engagement in either the survey or a school-prescribed alternative activity with a recognition reward, such as a pizza party.

STUDY DURATION

Estimate the probable duration of the entire study. This estimate should include the total time each subject is to be involved and the duration of each data collection about the subject.

E.G., This is a two-year study. Participants will be interviewed three times per year; each interview will last approximately two hours. Total approximate time commitment for participants is 12 hours.

Part 1: School Recruitment
This component is expected to last between 3-5 months. This is the period between initial outreach and school decision. However, data will be recorded only at the point where there was a final determination.

Part 2: Cognitive Interviews
Participants will undergo a 1-hour interview, after which no more data will be collected from them.

Part 3. Student Surveys
The cross-sectional student survey is an anonymous, one-time self-administered survey that lasts between 15 and 40 minutes.

Risks and Benefits

RISK DESCRIPTION

Provide a description of possible risks to participants: physical, psychological, social, economic, loss of data security, and/or loss of confidentiality. Describe and justify whether the research is minimal risk or greater than minimal risk.

Part 1: School Recruitment
The risk to the schools is minimal for participating in the school recruitment study. The request to participate in a survey is a normal and common occurrence for school staff in California. The decision will be made by a public agency and is disclosable under the California Public Records Act. As such, confidentiality will not be offered, nor would it be expected in normal school business.

The greatest risk to schools and school systems for participating is that they agree to participate in the survey, and parents view the survey as controversial. Our research group has had a report of a California school being disrupted by controversy over the inclusion of sexual orientation and gender identity (SOGI) questions on a student survey. The survey instrument in this submission contains SOGI questions, as required by California law (AB959 and AB957). This may create a substantial administrative cost for school administrators and psychological risks for teachers issuing the survey as a school representative and proctor. Teachers could be seen as responsible for exposing students in their community to harmful material. Our team has had schools experience notable costs related to controversies stemming from the administration of a survey with Sexual Orientation and Gender Identity questions.

Part 2. Cognitive Interviews
Participants will be asked to review questions that are similar in nature and content to passive parental consent surveys that are commonly issued to 7th-12th-grade students; the expected psychological risk to the interview informants is expected to be low and includes potential discomfort when discussing topics such as substance use and mental health. The greatest risk is that of loss of confidentiality regarding the participants' alcohol, tobacco, and cannabis use.

Part 3. Student Surveys
There are a few potential risks associated with this part of the study. Subjects may feel slightly uncomfortable disclosing their beliefs or knowledge about substance use or answering questions about their sexual orientation and gender identity; all of which are standard health behavior survey questions or are required by California law (AB959 and AB957). Students will be informed and reminded that answering questions is voluntary, and they may skip questions. Further, the data collected will be on anonymous online forms, which may lessen potential discomfort. While precautions are taken to ensure that the research data will be stored securely, a possible loss of confidentiality may occur if databases are compromised, and there are some rare constellations of student responses

that can potentially identify them. Because a full census has never been achieved, even with access to the original data, positive identification of a particular student cannot be made because there is no PID collected with the survey data. In public reports, tables with small cell sizes are omitted, collapsed, or jittered, to protect the confidentiality of students with rare demographic characteristics.

Because students are likely to complete their survey questionnaires on a school-managed electronic device, there is a risk that students' devices could be monitored remotely in real time or via screen captures actively by school staff or passively by the monitoring software. Information Technology leads at each school district must attest to securing the monitoring software during survey administration and providing means for UC San Diego to audit and document compliance with the monitoring software configuration agreement (Attachment 9: IT Letter of Assurance).

The survey contains no information likely to cause students harm or discomfort beyond what they encounter in daily life or during performance of routine examinations or tests, other than potentially some demographic questions about sexual orientation and gender identity, which are deemed benign enough to be required on all state-sponsored surveys. These are questions that students may skip. Therefore, this research meets the requirements to be considered “minimal risk” under federal regulations as defined in 45 CFR 46.404.

AUDIO/VIDEO RECORDING RISKS

State if audio/video taking could increase potential risk to subject's confidentiality.

Audio recordings will be made during the cognitive interviews. File names and associated data do not include participants' names. The interviewers are trained to avoid using the informant's name during the interview. Their names are stored in a participant database that is in a segregated system. The questions asked of the participant are not expected to result in identifying information. The greatest risk is if an audio recording was obtained through unauthorized access or release, and their voice was used to identify the informant. However, this risk is mitigated by limiting the storage of the file to two weeks or less and always storing it securely with limited access to only the transcriber and a senior staff reviewer.

Participants will be reminded that they can decline to answer any question that might be sensitive.

MEDICAL SERVICE RISKS

Describe how medical services will be provided if subjects suffer adverse mental or physical effects as result of research activity. If no services provided, state that clearly.

No medical services will be pre-arranged. For the student survey, the district lead for socio-emotional support or the school nurse will be contacted. They will be alerted to the survey, the administration date, and its contents. While the survey itself is of low risk, the larger sample size of the survey means that its administration may coincide with a mental health crisis. We will include the information that the district mental health leads provide and protocols for school staff to identify and intervene in mental health events.

No services will be provided by UCSD.

INTERNATIONAL RESEARCH

Will this research occur outside of the United States or U.S. territories?

Check with client to see if they consider territories to be outside the U.S. or not, as this can vary between institutions.

No

LESS RISKY METHODS

Describe any less risky methods and why they are not being used.

Part 1. School Recruitment
Prior formative research has been conducted to ask key informants during short interviews what they would expect regarding school decisions. This is deemed helpful, but insufficient for determining what a whole school system will decide without all of the interacting processes being engaged. The formative work was used to screen out administrative attributes that are unlikely to pass even an initial consideration. An acceptability estimate under any condition cannot be confidently determined without empirical data on schools' decisions.

Part 2. Cognitive Interviews
Internal reviews by trained staff can be useful for improving questionnaire design. Trained staff are not culturally and educationally equivalent to a diverse sample of California youth. We need to ask young people directly what they think about question wording.

Part 3. Student Survey
Passive methods exist for gauging some behaviors, such as wastewater assessments of drug metabolites. However, these have not been validated for high school students at this time. Assessing behavioral traces also leaves out substantial information regarding modes of use, social factors, perceptions, attitudes, and beliefs that can only be accessed in combination in a self-report assessment.

BENEFITS

Describe the benefits, if any, to the subjects or to society that will be realized as a result of this project. Discuss the benefits that may accrue directly to the subjects as well as to society. If there is no direct benefit anticipated for the subjects, state that clearly.

Part 1. School Recruitment
Schools may not benefit directly for their participation. In some instances, statistics generated by the survey will assist schools in obtaining information that is required for LCAP reporting, which is required for some forms of state funding. Schools may also benefit from obtaining quantified information about student behaviors that can help with identifying student needs and measuring school program impacts.

By quantifying the importance of different survey assistance and administration characteristics, future state-wide surveys can be designed that will be successful. More efficient efforts for the State of California and the most beneficial support for the schools are expected as a result of the proposed study.

Part 2. Cognitive Interviews
The informants will not receive any direct benefit. Society may benefit if the instruments are improved and the efforts behind the survey result information useful for public health resource allocation.

Part 3. Student Survey
Direct benefit to the students participating in the survey is unlikely. There may be some short-term indirect benefits at schools that survey whole grade levels and adjust their substance use intervention programming on campus as a result of the survey results. The survey pilot will also provide some preliminary data that may result in changes in public health practice.

JUSTIFICATION OF RISKS

Explain why study risks are reasonable in relation to the potential benefits to subjects and to society.

Quality estimates of youth risk behaviors and risk factors is important for the efficient allocation of public health resources and evaluation of programming and policy changes. Ensuring that the survey administration is acceptable for most schools requires quantifying the impact of key barriers in order to justify the minimally necessary resources and policy changes. Given that 1 in 10 adult Americans has experienced substance use disorder in their lifetime, and youth experience with substances is a risk factor for adult substance use problems (NESARC-III REF), the minimal risks to this study's participants are outweighed by the potential benefits.

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

If the researcher demonstrates that he or she is unable to comply with any of the requirements below, he or she may request an exception from these requirements. The researcher should indicate any measures that will be taken to address this requirement. The exception request should be made in the text box of the corresponding requirement. An exception will only be granted if the researcher can demonstrate that adequate alternative measures have been taken to minimize risks so as to justify the exception.

HIPAA IDENTIFIERS

Please identify which HIPAA Identifiers you plan to request as part of your submission.

Name
Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
Telephone numbers
Email address

TRAINING PROCEDURES

Describe the procedures for training all research staff who have access to PID on privacy and security. Indicate if staff are required to sign a confidentiality statement related to general use, security, and privacy.

All UCSD staff will have successfully completed CITI training. All staff involved in consenting and screening will have been oriented and assessed to ensure they have sufficient knowledge of the study to answer potential participants' questions. Staff with access to the participant contact database or research data will also be required to sign a confidentiality agreement

Part 3 Student Survey: No personal identifying information will be collected, such as name or address. Any public release of the findings will consist of aggregated data with no identification of individual participants.

STAFF VETTING PROCEDURES

Describe procedures, either background check or thorough reference check, for vetting staff who will have access to PID.

All UCSD staff are subject to background checks before employment. In addition, hiring managers and human resources staff conduct reference checks as part of candidate selection and finalization of offers of employment.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

This is a statement from the state agency or department you are receiving data from. It must be on that agency's/department's letterhead and should include both

1) *that the release of the desired data is legal and*

2) *that the entity is willing to release the desired data to you, the researcher. If you are not receiving data, this letter should indicate that you are supported.*

***For VSAC requests, if you do not have a Departmental Letter of Support (LOS)/Data Release, you may upload a copy of the Data Request Form (application) from the department to secure a review for the upcoming cycle. The protocol will not be approved until the LOS is uploaded to the protocol.*

Please also review the CPHS Statement for Birth and Death Data.

LOS_UCSD_CDPH.pdf Department Letter of Support

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PREVENTING RE-USE AND UNAUTHORIZED ACCESS

Explain how you will ensure that data will not be reused or provided to any unauthorized person or entity.

Unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS.

Unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS.

The research data will reside on Dr. Zhu's UC San Diego HIPAA compliant internal network drives. The data directories will be limited in terms of access to the project director, project statisticians, professional data processing RA, and senior system administrator. Those with access privileges will sign an agreement that the data will not be shared without prior approval of CDPH, unless release is required by law and release is consistent with this IRB approval and participants' informed consent.

All information on the computer will be protected through encryption and access to the system itself will be protected using strong passwords. Research records will be maintained on the secure computer system or in locked cabinets. No information will be published that could identify an individual participant. In addition, the Project Director will periodically review data from the records to ensure the safety of participants and to ensure the integrity of the research. No data will be open to the internet and all data transfers will be done securely. No data will be left unattended on the audio recording device. All devices will utilize encryption, as per UCSD HRPP SOPP. Computer access is protected through passwords and encryption. The servers are protected behind sophisticated firewalls with an extensive array of virus protection. The UCSD research team has over 20 years of experience conducting research, including storing and managing large amounts of sensitive information. It is foreseeable that this study will have access to or collection of information that Federal, State, and/or local laws/regulations require or may require to be reported to other officials or ethically require actions. The investigators are not "mandated reporters."

CONFIDENTIALITY OF PUBLISHED DATA

Indicate whether information will be published that could possibly be used to identify an individual subject.

No information will be published that could identify an individual participant. Any public release of the findings will consist of aggregated data with no identification of individual participants. Small table margins or cell sizes that could potentially compromise the actual or perceived confidentiality of a student will be avoided by censoring the table, collapsing cells together, or jittering the data.

DATA REQUEST JUSTIFICATION

Provide adequate justifications for the quantity of the data, the years and the variables being requested. Have you requested no more than the minimum necessary data to perform the research?

The planned sample sizes are for the minimum that might be necessary to have a reasonable probability of detecting differences. The primary sampling unit is the school for Part 1 (and Part 3). Without adaptive sampling this number would be too small to be meaningful for the dichotomous outcome of interest. Sampling entire school grade levels (10th and 12th grade) is necessary for the data to be locally valuable, particularly when considering that minority demographic groups of interest would have small cell sizes in subsamples of grade levels. Further, sampling a few classrooms is not adequate for characterizing a school. Based on our study design, we require sufficient data to be representative of the target population, which serves as the minimum necessary data to capture the most current trends in substance use among youth.

LIMITATIONS TO DATA ACCESS

Indicate if access to data is limited only to those with a need to know for purposes of implementing or evaluating the research.

Full access to the electronic files will only be available to the Principal Investigator, Project Director, Project Manager, and system administrators. Research associates will be granted access to data that is necessary for their work.

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

Describe appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

Data will not be linked to other microdata and will be reported in aggregated form. Additional safeguarding procedures include: 1) A master code log linking assigned code to basic participant demographic information only (i.e., gender, ethnicity) will be retained in a password-protected electronic file accessible only to the Principal Investigator, Project Director, Project Statistician, and System Administrator or, on an as-need limited basis, professional research associates. 2) All identifying information in the contact database will be encrypted, password protected, and stored on separate system from observations database. 3) The mapping key linking databases will be destroyed at the end of the study period.

LINKAGES

Will the data set be linked with any other data sets?

No

DESTRUCTION OF PID VERIFICATION

Indicate that you will provide CPHS with a letter certifying that PID has been destroyed and/or returned to the data source once research is concluded.

Yes

DATA SECURITY LETTER

Upload a certification/statement from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.

- *Data security letters cannot be signed by the Principal Investigator or Responsible Official.*
- *The data security letter must be on your institution's letterhead.*
- *Example of data security letter*

IRB - Cannabis - Data Security Letter.pdf Data Security Letter

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Physical Safeguards

DATA PROTECTION

Indicate that research records and physical samples will be protected through the use of locked cabinets and locked rooms; PID in paper form will not be left unattended unless locked in a file cabinet, file room, desk, or office.

Yes

DATA DESTRUCTION

Will data/samples will be destroyed or returned as soon as it is no longer needed for the research project.

Yes

RETAINED DATA

Will the retained data/samples have personal identifiers or be de-identified?

data will be de-identified

Explain what identifiers will be removed and how.
Observation data are never stored with PID. The participant contact database and screener database will be erased immediately upon completion of the data collection and data review.

DESTRUCTION METHODS

Describe how you will ensure the PID in paper form is disposed of through confidential means, such as cross cut shredding or pulverizing.

The only paper forms with PID are consent forms. These will be cross-cut shredded or to UC San Diego Health System compliant specifications, whichever is stronger, after the consent form retention period has expired.

FAXING

Describe how you will ensure that faxes with PID are not left unattended and fax machines are in secure areas.

There are no plans to have PID transmitted by FAX. It will be against policy to do so.

MAILING

Indicate whether mailings of PID are sealed and secured from inappropriate viewing; and whether mailings of 500 or more individually identifiable records of PID in a single package, and all mailings of PID to vendors/contractors/co-researchers, are sent using a tracked mailing method, which includes verification of delivery and receipt, such as UPS, U.S. Express Mail, or Federal Express, or by bonded courier.

Only signed consent forms will be sent by certified courier or delivery. They will be held in HIPAA compliant packaging.

ELECTRONIC STORAGE

State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will ever be left unattended in cars or other unsecured locations.

No PID will be stored on laptop drives or portable storage.

PHYSICAL STORAGE

Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.

Data will be stored on UCSD's Amazon Web Services (AWS) cloud which has controlled
physical access as well as security monitoring and surveillance detection.

SERVER SECURITY

Provide a description of whether all servers containing unencrypted PID are housed in a secure room with controlled access procedures.

Any PID will be encrypted.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Personal identifiers will be stored on a separate system. Observations will be stored separately and only include mapping variables to records in the contact database which are mapped by hand, so the observation data are not merged with the research observation data.

DISK STORAGE

State whether all disks with PID will be destroyed.

At the end of the project, data will be downloaded from AWS and kept in cold storage on an encrypted drive stored locally in an access-limited secure server room.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

State whether all computer access will be protected through the use of encryption, passwords, and other protections.

All PCs and Servers are encrypted and comply to UCSD minimum network standards which includes password protection: https://blink.ucsd.edu/technology/security/policies/standards.html

FIPS 140-2 COMPLIANCE: WORKSTATIONS

Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

All workstations use Bitlocker configured to be FIPS 140-2 compliant.

FIPS 140-2 COMPLIANCE: LAPTOPS

Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

All laptops use Bitlocker configured to be FIPS 140-2 compliant.

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

Indicate if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup recordings) are encrypted with software that is FIPS 140-2 compliant.

USB ports are disabled for removable storage and are prevented from data transfer.

SECURITY PATCHES

Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

All workstations, laptops and servers are automatically patched.

PASSWORD CONTROLS

Indicate if sufficiently strong password controls are in place to protect PID stored on workstations, laptops, servers, and removable media.

Password controls follow UCSD policy: https://blink.ucsd.edu/technology/network/access/secure-passwords.html#password-standards

ELECTRONIC SECURITY CONTROLS

Indicate if sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews.

Security controls for timeout, audits, anti-virus are outlined in the UCSD minimum network standards

FIPS 140-2 COMPLIANCE: ELECTRONIC TRANSMISSION

Explain whether all transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.

PID is not shared outside of our lab by policy with the exception of the use of Airtable.

All data transmitted between Airtable users and servers is encrypted in transit using TLSv1.2 or higher with 256-bit SSL/TLS encryption, and data stored within Airtable is encrypted at rest using AES-256 encryption. These encryption methods are consistent with FIPS 140-2 validated algorithms.

INTERNET ACCESSIBILITY

Note if PID in an electronic form will be accessible to the internet.

Participant contact information is stored on the cloud service Airtable. No research observation data or sensitive information is included in those data. Data are held on tables that are accessible only to the UC San Diego team members who use the data in their regular roles. Strong passwords and two-factor authentication will be used. Data are encrypted in transit and while at rest.

DISPOSING OF PID

When disposing of electronic PID, indicate whether sufficiently secure wiping, degaussing, or physical destruction will be used.

At the conclusion of the project, research participants' PID will be promptly deleted unless participants consent to have their contact information retained for possible future research opportunities or to be contacted with information about the research project's findings or impacts. These data will be retained for a limited period not to exceed 7 years. PID, which is no longer actively used, will be moved to cold storage on encrypted drive(s) stored in our limited-access locked cabinets. Drives will be securely erased when the data has expired or is no longer needed for the research or by policy. All agencies overseeing this research will be notified when the PID data has been securely erased.

Conflict of Interest Information

CONFLICT OF INTEREST (COI) INSTRUCTIONS

A COI is defined as any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings. Researchers must disclose any COI, including perceived COI.

Financial relationships to be disclosed include but are not limited to the following:

- **Present or anticipated ownership of stock, stock options, or other financial obligations of the source of funding.**
- **Receipt or expectation of payment of any sort in connection with papers, symposia, consulting, editing, etc. from the source of funding.**
- **The sale or licensing or anticipated sale or licensing of medical or other products or intellectual property, such as patents, copyrights, or trade secrets to the source of funding or other entities.**
- **Any past, present or anticipated receipt of money or other valuable consideration from the source of research funding by the researcher(s), the family of the researcher(s), the research institution, or by an institution in which the researcher(s) or the family of the researcher(s) has an interest as owner, creditor, or officer.**

DISCLOSURES

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the above-referenced project?

No

Informed Consent Procedures

INFORMED CONSENT PROCEDURES

Provide a description of procedures to be used in obtaining and documenting informed consent from participants.

See instructions and examples on CPHS website.

Part 1: School Recruitment
The level of analysis and observation is the school system. The observation being recorded is the school's decision, which can be finalized at many levels in the organization, and acceptance typically involves the interaction of multiple levels (e.g., school leadership, teachers, behavioral health staff, district office leadership, and school board of directors). Typically, recruitment efforts by UCSD are primarily directed at a school's designated or de facto point of contact, who is not always identifiable until after contact is established with the organization.

The consent process will work as follows:
UCSD will send a query to the school in the form of a written correspondence and a phone call. The query will function as an advertisement to let the school know about the opportunity for participation (See Attachment 5: Initial School Contact). This initial correspondence and call start the effort of finding the appropriate point of contact who can provisionally consider the school's interest, gather appropriate information, and then communicate with and obtain a decision from the school system.

If schools respond with a request for more information or express interest in the research, a follow-up email will be sent. If a phone call is requested, it will be scheduled and preceded by the sending of a follow-up email. The follow-up email will be sent to the original recipient of the advertisement or to the person(s) identified by the school as the appropriate person(s) to contact. The follow-up email will provide for written informed consent. It will contain information about the survey, including its purpose, the benefits, the risks, what to expect, and who to contact if questions or issues arise (Attachment 6: School Recruitment Consent Emails). The email will also notify the recipients that recruitment is being studied, their decision will be recorded, and that schools are being offered different administration packages. They will be informed that nothing will be expected of them as part of that study beyond processing the invitation as they would if the research project dropped the package randomization from the study. They will also be informed that they can choose not to participate. In this case, they will still be eligible to hold the student survey, but their school's decision will not be recorded.

Some schools will not be fully informed initially. Upon making a decision, schools randomized to the limited support packages will be debriefed. They will be informed that they had been offered less than what will actually be provided. Schools will be informed that they can access the options provided in the other packages (except quick reporting, which may not be able to be scaled up without additional funding). This will also be disclosed if a school reports that they have identified an important requirement during their decision-making that can be addressed with a package attribute they had

not yet been offered.
Approval for an alteration of informed consent and deception is being sought for this protocol.

Part 2: Cognitive Interviews
At the time of scheduling an online interview, participants will be issued a DocuSign version of the written informed consent (Attachment 10: Cognitive Interview Consent). They will be given time to read and ask questions about the study before being asked to digitally sign the consent. For participants that are interviewed in person, they will be emailed the consent form at the time of scheduling. They will be encouraged to ask questions via phone or email. The consent will be reviewed with the participant when they first arrive for the interview. After answering the participants' questions about the study they will be asked to sign the consent before the interview starts.

Part 3: Student Surveys
All schools will be provided with written consent and assent forms (Attachment 11 & 12) for the schools to distribute to parents/guardians of students in 10th and 12th grade. Both English and Spanish versions will be distributed together (e.g., one side in English and the other side in Spanish). Written instructions will be provided to the school-designated coordinator regarding the procedure for collecting any consent forms needed, and the UCSD project manager will be available to answer questions and address problems. The UCSD project manager will also be charged with reviewing that each school's consent and training procedure has been correctly implemented prior to survey administration at a particular school.

Schools will be required to distribute the consent form at least two weeks in advance of the survey date. Schools will send confirmations of refusal receipt to parents. Schools will also be required to make an all call notice the day before the survey. An all call is a notice using parents’ preferred mode of contact (if specified), either by phone, text, or email, to all the registered parents of students at a school. The call will remind parents of the survey, how to opt their child out, and let them know how refusals submissions were confirmed. UCSD will track refusals and audit schools' confirmation of receipt process.

CONSENT FORMS

Attach copies of consent forms and any other documents or oral scripts used to inform potential research subjects about the study. See examples of consent and assent forms on the CPHS website.

Be sure to include a concise explanation of key information for participants at the beginning of your consent form, as shown in the examples on the website. Also attach the Participant's Bill of Rights (download the revised version from the same CPHS website). CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent. If a waiver or alteration of informed consent is being requested, attach a document that explains how all of the criteria below will be satisfied.

10.MYHBf.CognitiveInterviewConsent.docx	Consent Form
11.MYHBf.ParentConsent.docx	Consent Form
CPHSBillofRightsNonMed.pdf	Consent Form

Deleted Attachments: 3 (Most Recent: 10.MYHBf.CognitiveInterviewConsent.docx on 09/04/2025 6:51 PM ET)

ASSENT PROCEDURES

Provide a description of procedures to be used in obtaining and documenting informed assent from participants.

See instructions and examples on the CPHS website.

Part 1: NA
Part 2: NA
Part 3: Student Survey
Students under the age of 18 who have parental permission to take the survey will be informed and assessed in two ways. Just before the survey begins, the proctors will read a script that outlines the survey's purpose and content, what they can expect, the risks, and that the survey is voluntary. This information is repeated in writing on the first page of the survey. Students must affirm that they assent to be able to see any of the survey questions.

At the start of the survey, proctors will read aloud the assent document written at the 6th-grade reading level (Attachment 10). The script explains the nature and length of the survey, benefits and risks of participation, safeguards for the data, and that participation is voluntary. It states that students can opt out at any time. The script and assent forms are attached.

ASSENT FORMS

Attach copies of assent forms and any other documents or oral scripts used to inform potential research subjects about the study. See examples of consent and assent forms on the CPHS website. Be sure to include a concise explanation of key information for participants at the beginning of your assent form, as shown in the examples on the website. Also attach the Participant's Bill of Rights (download the revised version from the CPHS website).

Assent forms must be understandable to children who are 7-17 years of age. However, the same elements that are required in a consent form must be adequately covered in an assent form. The reading level must be age appropriate, and a shortened form may be needed for younger children or those with more limited reading ability. Thus, different versions of the assent form may be needed if the study involves children of significantly different ages. A question-and-answer format, as shown in the CPHS example of an assent form, may be especially appropriate.

12.MYHBf.StudentAssent.docx Assent Forms

Deleted Attachments: 2 (Most Recent: 12.MYHBf.StudentAssent.docx on 09/04/2025 6:54 PM ET)

Informed Consent Waiver

INFORMED CONSENT WAIVER

Are you requesting a waiver or alteration of informed consent?

Yes

Provide a rationale as to why the research could not practicably be conducted without the waiver or alteration.
Part 1: School Recruitment Study
School recruitment will follow the same process used for our prior MyHB, CYTS, and CHKS surveys. However, because we are now planning to systematically evaluate different administration packages on school systems' interest in participation, those recruitment activities may be considered human subjects research.

It would not be feasible to first recruit all the members of school leadership networks to a study of their decisions regarding a school survey. Our formative research has identified the distraction and administrative burden of running surveys is one of the important deterrents for schools to participate in surveys. Attempting to identify, track, and consent all of the members would be an additional substantial burden on the schools. The process would likely impact the decision-making process and ultimately the decision schools make. The schools that participate in the recruitment study will likely be unrepresentative of California as a whole.

The proposed alternative is to inform the main point of contact at each school that the survey administration packages are under study and allow the point of contact to opt out of the school recruitment study. Once the point of contact at a school is established, they will be informed about the details of the survey to be conducted at their school. As part of that written invitation, they would be notified that the school's ultimate decision was being studied. The purpose of collecting data on decisions will be described. The absence of additional risks and benefits will also be outlined. In addition, how to opt out of participation and contact the IRB will be included. Finally, it will be noted that the school staff is not expected to do anything differently than they do when they are contacted by any of the other survey organizations that regularly run school-based surveys in California.

Part 3: Student Survey
We are requesting a waiver of documented parental consent for the administration of this anonymous survey. This project meets the requirements for a waiver of parental consent:

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

The impracticality of obtaining signed consent from tens of thousands of

parents in multiple school districts was addressed by the California Education Code. According to California Education Code (51938), all students grades 6 and below must have active consent from their parent/guardian in order to take a survey, whereas active consent is optional in grades 7-12, providing the survey is "anonymous, voluntary, and confidential" and measures "pupils' health behaviors and risks." Additionally, the law stipulates that the parent or guardian is notified in writing that this questionnaire is to be administered, and the pupil's parent or guardian is given the opportunity to review the questionnaire and to request in writing that his or her child not participate. The proposed survey questionnaire meets the provisions of the law (anonymous, voluntary, and confidential) and we will follow the stipulations named (written parental notification; opportunity to review a copy of the survey in the school office; and, providing a form to request in writing that child not participate, i.e., passive consent). We will also require schools to allow parents to email or call the school to opt their child out of the survey. Additionally, we will comply with each school district's approved consent policy.

We are also requesting a waiver of documented student assent and proposing to read an oral assent script. This project meets the requirements for oral assent in that:

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

The current proposal results in no student PID being collected and retained. There is no way to determine which students provided the data that is collected by the research team. The current process requires students to actively assent to proceed with the survey. The collection of signed assents would create associated data that holds all the participating students' names, which will not exist otherwise.

Provide a detailed account of the plans and measures that will be in place to protect the rights and welfare of the subjects.
The rights and welfare of participants and members of the school community will be protected in multiple ways:

Participants and minors' parents/guardians will be provided information about the nature and risks of participation.
Parents/guardians will be given multiple modes and ample opportunity to opt their child out. Parents/guardians will be informed at least twice using at least two modes of communication about the survey and how to opt their child out. In addition, minors will be required to give their informed assent.

School administrators and staff will be provided with detailed information about the nature of the study, except for the initial omission of additional assistance and service that will be provided if schools participate. Staff will maintain contact with participating schools. If a scenario develops where a risk to the school develops because of this omission, full disclosure will be

provided without further delay. Further, the protocol has been designed to collect no more information about the schools than would be collected if Aim 1 were not under investigation.

Will the subjects will be provided with additional information about their participation?

The intent of this waiver criterion is to require debriefing for participants in deception research.

Yes

HIPAA Determination

HIPAA INSTRUCTIONS

To determine if this project is covered by HIPAA, answer the following questions.

COVERED ENTITY

Will health information be obtained from a covered entity, known as a clearinghouse, such as Blue Cross, that processes or facilitates processing health data from another entity, including but not limited to state databases?

No

HEALTHCARE PROVISIONS

Will the study involve the provision of healthcare by a covered entity, such as the UCD Medical Center?

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

24-10407 STD 213 EXECUTED - Budget only.pdf Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

09 04 25 - Signed Letterhead - IRB Cover Letter - Survey.pdf Cover Letter

To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this application is accurate and reflects the proposed research and that you attest to the conflict of interest disclosures for all study team members.

Signed Friday, September 5, 2025 3:25:34 PM ET by Shu-Hong Zhu, PhD

In order to submit this form, click "Next" and "Submit." At that time, the application will be routed to the Responsible Official (if this is the first submission) for review and signature.

Responsible Official Signature
- Submitted 09/11/2025 4:31 PM ET by Cheryl Anderson, PhD

Responsible Official Signature

After reviewing this application, is it ready for submission to the CPHS IRB?

Yes, ready for submission to IRB.

Enter your password to sign this protocol. By signing this protocol, you are attesting that the information within is accurate and reflects the details of the proposed research project.

Signed Thursday, September 11, 2025 4:31:47 PM ET by Cheryl Anderson, PhD

After choosing whether or not the submission is ready for CPHS IRB review, please click "next" and "submit" (on the next screen) to move the form forward to the CPHS IRB or back to the Researcher.

Notify IRB for Pre-Screening
- Submitted 09/12/2025 11:32 AM ET by Nicholas Zadrozna

Internal IRB Screening

CPHS Office: The questions on this page will appear every time the project is resubmitted to the CPHS IRB (even after review). Once the project has been reviewed by a committee member, unless researcher has changed questions on the form that impact the level of review, you do not need to update the questions here. If the changes made are not clear and require additional clarification change the 'ready for review' to 'no' and require changes. When you change the answer back to yes, it will remember your previous answers.

Is this study ready to be reviewed by the CPHS panel?

Yes

Choose the IRB committee to review this study (this defaults to CPHS)

CPHS

Level of Review Determination (once the level of review is assigned for this project, do not change this answer unless the reviewer/committee has decided that the study requires a different level of review)

Full Board Minimal Risk

Please provide a rationale for your level of review preliminary determination
This project will be reviewed during the October full board meeting.

Choose the CPHS Chair
Catherine Hess, PhD

Select the vice chair of the committee
Larry Dickey, MD, MPH, MSW

Assign to Cycle

October

Assign to cycle year
2025

Load into IRBManager (Initial Submission)
- Submitted 09/12/2025 11:33 AM ET by The System

Chair Review and Full Board Set-Up
- Submitted 09/12/2025 11:37 AM ET by Nicholas Zadrozna

Full Board Set Up

Project number

2025-144

The office will complete the questions on this page and submit the form after the teleconference with the chairs regarding this project is completed.

Confirmation of level of review

Full Board Minimal Risk

Provide the rationale for the level of review determination
The project will need to be reviewed for the October full board meeting.

Assign SME to study

Larry Dickey, MD, MPH, MSW

Enter the meeting date for this project

10/03/2025

SME Review

SME review

After reviewing the application, complete the question(s) below. If you wish to make comments on the application for the researcher, use the 'add note' feature on each question (be certain to unmark the internal only box and do not mark changes required). To navigate the application, you can either use the 'previous' button at the bottom of the page or from the drop down at the top of this page choose 'view previous stages'. Once you have completed the questions that appear on this page (different questions will appear depending on your answer to the first question), you will need to click 'next' (from either the top of the bottom of the screen) and then click 'submit'.

If you are requiring revisions before the full committee review, the form will be returned to the researcher for revisions and returned to you upon re-submission.

Does the researcher need to provide additional information/revisions before the committee meeting? If there is insufficient time for the researcher to make changes prior to the committee meeting, choose 'no' in order to route the form correctly.

No answer provided.

In order to either return this application to the researcher or to move forward for the full meeting review, click 'next' and 'submit' on the next screen.