

View xForm - Project Application v6

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

Data entry

- Submitted 09/02/2025 2:48 PM ET by Kathleen Tebb, PhD

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

October 2025 cycle

09/08/2025 • Nicholas Zadrozna • Internal

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.

Kathleen Tebb, PhD

Email: kathleen.tebb@ucsf.edu **Business:** (707) 290-7829

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

University of California, San Francisco

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

San Francisco

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.

Tebb CV_ABRV_ 2024.pdf 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.

Katelyn Wiliford, BA

Email: Katelyn.Williford@tcoe.org **Business:** (559) 733-6496

Nani Dodson, BS

Email: nanid@tcoe.org **Business:** (559) 733-6496

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.

Sara Buckelew, MD

Email: sara.buckelew@ucsf.edu **Business:** (415) 502-1649

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.

No answer provided.

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

False

Project Information

SUBMITTER

Application completed by:

Kathleen Tebb, PhD

Email: kathleen.tebb@ucsf.edu **Business:** (707) 290-7829

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).

Assessment and Evaluation for Youth Alcohol Access

PROJECT SITE

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

Friday Night Live Programs

STUDY PROCEDURES

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

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 <u>outside</u> the CHHSA (e.g. California Department of Corrections and Rehabilitation [CDCR], California Department of Education [CDE], etc.) **OR** studies requesting data <u>within</u> 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 <u>within</u> 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

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

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.

State funded

Enter name of state-funded source.

California Department of Public Health

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

10/06/2025

ANTICIPATED PROJECT END DATE

10/06/2025

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.

Adolescents' use of alcohol, tobacco, and other drugs (ATOD) is a critical public

health issue [1]. ATOD use is a leading cause of preventable morbidity and mortality

among adolescents and increases the risk of academic, psycho-social, physical, mental,

and sexual health problems as well as accidents and unintentional injuries and can cause

detrimental changes in brain development [2–4]. Alcohol use and binge drinking among

U.S. high school students remains high, and 17% report riding with a driver who had been

drinking [5,6]. Use of alcohol at an early age is associated with alcohol-related problems in

adulthood [7]. Among those who began drinking under 14 years of age, 45% developed a

dependence on alcohol later in life, and if alcohol initiation was delayed to over 21 years,

lifetime alcohol dependence dropped to 10% [8]. The purpose of this study is to develop and implement an annoynomus survey of approximatley 1,500 adolescents from California, to assess their knowledge, attitudes, social norms, and perceptions of underage alcohol use and harm prevention to inform the types of materials and programs that would best benefit the youth of California. Research will also include an assessment of co-use of alcohol and cannabis products by youth.

MAJOR RESEARCH QUESTION

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

What are California's adolescents knowledge and attitudes toward underage alcohol use and related behaviors?

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

Youth participating in 43 Friday Night Live Program chapters will be asked to distribute a link (via flyer, text, or social media) to an anonymous survey to their peers. The survey is anonymous and voluntary. The survey will assesses adolescents', between the ages of 13-20 years of age, alcohol knowledge, attitudes and behaviors. Potential participants will be informed the following (see also intro to the attached survey) "this survey is part of a voluntary research study that will help us better understand youth attitudes about alcohol and underage drinking. You do not have to take this survey. If you do not want to participate, do not fill out this survey. All of your answers are completely anonymous – we are not collecting any information that can identify you. Please answer each question as honestly as you can. You can skip any question you do not want to answer. If you do not know an answer, that is okay - just mark that you don't know." When youth are finished wiht the survey they will be entered into a drawing to receive one of fifty, \$50 gifts cards. Youth will be informed that we estimate that approximatley 1,500 youth from across California will take this survey.

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.

2025 YOUTH ALCOHOL SURVEY FINAL 7.1.25.docx Questionnaires
2025 Alcohol Survey Flyer.pdf Recruitment Materials

RECORDING
Will audio or video recording occur?
No

DECEPTION
Will deception be used in this study?
,
No

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.

1,500 adolescents between the ages of 13 and 20 years of age. Because we are using snowball sampling of youth in Friday Night Live programs from across the state of California, we hope to get a diverse sample of adolescents who are similar to the demographics of youth in California.

RATIONALE

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

Utilizing youth in 45 Friday Night Live Chapters was deemed the most convenient and cost-effective approach to reach a large sample of diverse California youth.

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.

The adult advisors in the Friday Night Live programs will ask youth in their programs, as part of their community outreach efforts, to distribute links/QR codes to their peers. Attached is a sample flyer youth can distribute to their peers via social media, text, or paper format.

Attach copies of all recruitment materials.

2025 Alcohol Survey Flyer.pdf Recruitment Materials

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.

The survey will only allow adolescents from California between the ages of 13 and 20 years old to participate.

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type

Gift card

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.

Participants who wish to be entered into a drawing for one of 50, \$50 gift cards will be asked to click on a link to a new survey to enter their contact information. This new link will ensure there are no identifiers on the survey, and the survey responses remain anonymous. It also allows us to ensure that there is only 1 entry per survey respondent.

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.

The survey contains 36 items which are estimated to take between 25 and 30 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.

This survey is a minimal risk because it is both anonymous and voluntary. Some questions, especially around alcohol use, may make participants feel uncomortable; however, they can skil any question they wish and can stop the survey at any time.

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.

Ther is no medical risk to participating in this study.

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.

There are no other less risky methods to assess adolescents knowledge, attitudes and alcohol use behaviors.

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.

The data gathered from this study will be used to inform CDPH's underage alcohol use prevention programming.

JUSTIFICATION OF RISKS

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

Underage alcohol use is a major public health issue. This survey will gather important information, from California's adolescents to inform public health prevention strategies.

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 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.

The only PHI we will obtain are to enter participants into a drawing for a gift card. We will ask for their name and the best way to send them the gift card if they are selected from the random drawing (text or e-mail). If they do not have a phone or e-mail, we will ask for their physical mailing address. All personnel at UCSF must complete the UCSF human subjects protection training on the Collaborative Institutional Training Initiative (CITI) website. Staff will not be required to sign a confidentiality statement related to general use, security, and privacy as this is covered in their training.

STAFF VETTING PROCEDURES

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

Only the PI from UCSF will conduct the random drawing will have access to PHI. While participants will complete the anonymous survey via SurveyMonkey administered by TCOE, Friday Night Live Partnership, participants who want to enter the drawing will click on a link that will direct them to a UCSF Qualtrics, secure survey, to collect their PHI. The PI and all UCSF staff went through a hiring process that includes a reference and background check.

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.

Not Applicable.pdf Department Letter of Support

Deleted Attachments: 1 (Most Recent: CPHS_Data_Security_Letter.pdf on 07/09/2025 6:31 PM ET)

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.

In addition to the protections previously described, the participant contact information for the purposes of the gift card, is stored on an encrypted/password protected computer that only the UCSF PI will have access to. No other person will have access to this information. The PI will only contact those participants selected from the drawing. All PHI will be destroyed after the drawing is complete.

CONFIDENTIALITY OF PUBLISHED DATA

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

If information is published, it will not contain any information that could potentially identify an individual participant.

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 duration of this study is one year.

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.

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

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.

not applicable

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

CPHS_Data_Security_Letter.pdf Data Security Letter

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 deidentified?

data will contain personal identifiers

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 data is stored electronically in Qualtrics, a UCSF approved secure on-line survey system, it is not linked to any survey responses (noted in application). PHI will be deleted from Qualtrics and the computer used to conduct the random drawing as soon as the drawing has been completed.

FAXING

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

Not applicable

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.

not applicable

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.

PID stored on the UCSF secured laptop will never be left unattended.

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.

UCSF has 24-hour security guard, UCSF authorized identification card is required to enter the building and to use the elevators.

SERVER SECURITY

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

There is no unencrypted PID stored on UCSF servers.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Not applicable, the survey and PHI are not linked in anyway.

DISK STORAGE

State whether all disks with PID will be destroyed.

Not applicable

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

The UCSF computer used for this project utilizes encryption, is password protected and uses a Duo Security that serves as a two-factor authentication tool to access the computer.

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.

Not applicable, work stations are not used for this study.

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 that contain PID have full disc encryption that uses FIPS 140-2 compliant software.

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.

not applicable, PID will not be stored on removable media devices.

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.

UCSF has regularly requires users to install security patches.

PASSWORD CONTROLS

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

UCSF requires strong password controls including 12 characters, and a combination of upper case and lower case letters, numbers and symbols, which must be changed on an annual basis.

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.

On battery power the screen time out control is 4 minutes, when plugged in it is 10 minutes. UCSF maintains secure systems with anti-virus updates.

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.

Participants will be notified if they have been selected through secure e-mail. If they do not have an email, they will be notified via SMS, if they do not have SMS then they will be sent their gift card via regular mail.

INTERNET ACCESSIBILITY

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

There is no internet access.

DISPOSING OF PID

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

Electronic PID data in qualtrics will be deleted using their deletion tool. Any electronic PID data on the computer will be destroyed using Eraser software to ensure no data is stored on the hard drive.

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.

Participants will be informed on the electronic survey that the survey is anonymous, voluntary, and they can skip any item they wish and stop the survey at any time. Selecting continue is confirmation that they consent to participate. See language on the attached survey.

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.

2025 YOUTH ALCOHOL SURVEY FINAL 7.1.25.docx Consent Form

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

Request for Quote_UCSF_Tebb.pdf Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

CPHSCoverLetter_Tebb2025.doc 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 Tuesday, September 2, 2025 2:47:57 PM ET by Kathleen Tebb, 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 09/07/2025 3:14 PM ET by Sara Buckelew, MD

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 Sunday, September 7, 2025 3:14:01 PM ET by Sara Buckelew, MD

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

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?

No answer provided.

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