

View xForm - Project Application v6

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

Data entry

- Submitted 04/30/2026 5:57 AM ET by Danny Azucar, PhD, MPH

Amendment Header

Amendment Submitter

Danny Azucar, PhD, MPH

Email: dazucar@rescueagency.com **Business:** (619) 231-7555

Instructions for amending your approved application:

This is a copy of the project application in order to amend the project. You must answer all the amendment questions. After you've answered those questions, you will have to update all answers on the form that related to your proposed changes. You may leave other questions with their original answer. If you do not update the appropriate responses on the form related to your proposed amendment, you will be required to make additional changes.

Note that the contacts listed on this page are output only questions that cannot be changed. If you need to request personnel changes, you will be prompted later on within this form to enter the new contact information.

PI:

Danny Azucar, PhD, MPH

Email: dazucar@rescueagency.com **Business:** (619) 231-7555

Administrative Contacts:

Name	Role
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Protocol Number:

2025-178

Protocol Title:

Understanding Attitudes, Perceptions, and Behaviors toward Youth Cannabis Use in California

Indicate what types of changes you are requesting to this project. Select all that apply

Other (examples such as, but not limited to: budget changes, project site and project title)

Clearly summarize and justify your proposed changes to the protocol in layman's terms for all selections made above

We are requesting approval to increase participant incentives for this study. Specifically, we propose increasing the incentive for teen participants from \$40 to \$75, and for young adult participants from \$75 to \$100.

This change is being made to support successful recruitment and ensure the study can meet its objectives. To date, recruitment has been challenging, and feedback from our recruitment vendor indicates that the current incentive amounts are below typical market rates for similar studies (which often average around \$150). In addition, some potential participants have indicated that the current incentive is not sufficient to motivate their participation.

By increasing the incentive amounts, we aim to improve participation rates, reduce recruitment delays, and ensure that we are able to gather the necessary data to complete the study as planned. This adjustment will help us use available funds more effectively by supporting timely recruitment and successful study completion.

Indicate the Level of Risk involved with the changes proposed.

If level of risk has changed, please update the "Risks" section in the protocol form.

Level of Risk has not changed

PI City Output *(Internal)*

San Diego

PI Location State Output *(Internal)*

California

Personnel Information for Amendment

Please complete the questions below.

If while trying to complete those questions, personnel are not found by their email address, you can add them in the system by completing the 'new contact form'. Click on the 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.

New Contact Form

Existing Personnel

Name	Role
Allison Parsons, PhD	Research Team
Danny Azucar, PhD, MPH	Research Team
Danny Azucar, PhD, MPH	Principal Investigator
Dawnyéa Jackson, PhD	Responsible Official
Josh Causey, BSc	Research Team
Molly Barry, MS	Research Team
Priscilla Fernandez, PhD	Research Team
Samantha Jacobs, MPH	Research Team
Shiloh Beckerley, PhD	Research Team

Will you be making any changes to the makeup of research personnel?

*No change in personnel

Project Information

SUBMITTER

Application completed by:

Danny Azucar, PhD, MPH

Email: dazucar@rescueagency.com **Business:** (619) 231-7555

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).

Understanding Attitudes, Perceptions, and Behaviors toward Youth Cannabis Use in California

STUDY PROCEDURES

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

Focus Groups
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

Non-English translation required

Consent form

Assent form

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, Substance and Addiction Prevention Branch

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

12/15/2025

ANTICIPATED PROJECT END DATE

12/15/2027

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.

The legalization of adult-use cannabis in California under Proposition 64 (2018) increased access and normalization. Though intended for adults 21 and older, these changes may affect youth perceptions and behaviors. About 12.8% of California high school students report past 30-day cannabis use, and 3% report heavy use. Research shows legalization is linked to higher adolescent and young-adult use and lower perceived risk.

Adolescent cannabis use poses developmental and behavioral risks. Early or frequent use can affect memory, attention, and learning, and is associated with poorer academic performance, increased risk of psychosis, and higher rates of cannabis use disorder. Because youth exposure and availability are growing, prevention strategies tailored to California's changing cannabis environment are needed.

Rescue Agency, in partnership with the California Department of Public Health – Substance and Addiction Prevention Branch (CDPH-SAPB), will conduct research to guide a statewide media and social marketing campaign aimed at educating youth and parents about cannabis risks, promoting healthy social norms, and improving parent-teen communication.

The study includes three phases with teens, young adults, and parents/caregivers across California:

- Phase 1 – Formative Research (up to N=156): Explore current attitudes, perceptions, and behaviors around cannabis.
- Phase 2 – Message Testing (up to N=126): Evaluate and refine educational messages and campaign concepts.
- Phase 3 – Red Flag Testing (up to N=54): Identify and address any unintended interpretations before launch.

All research will be conducted virtually, on Zoom, by Rescue Agency, with participants recruited statewide through online panels, social media, community outreach, and snowball sampling. Teen and young-adult sessions will be in English; parent/caregiver sessions will be in English and Spanish. Spanish materials are included in this application, yet other Spanish materials for Phase 1 and future instruments for Phase 2 and 3 will be submitted in later amendments as earlier results inform new phases.

The project, led and managed by Rescue Agency, will result in a scientifically grounded, statewide prevention campaign, with findings summarized in reports and related publications.

MAJOR RESEARCH QUESTION

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

What are the knowledge, attitudes, beliefs and perceptions of youth cannabis use in California? What social norms, values, social activities, and/or environments are more likely to encourage or discourage cannabis use? What type, style, and tone of educational messaging resonates with the various audiences and increases willingness to prevent or delay cannabis initiation, frequent cannabis use and/or safe and responsible use for those of legal age?

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

Phase 1 - Formative Research, Focus Groups

Phase 1 qualitative formative research will be composed of focus groups, a check-in survey, and a statement survey for three distinct audiences - teens (13–17), young adults (18–20), and parents/caregivers of children and teens 11–17. The teen audience will be composed of 12 focus groups of 3–8 participants each, while the young adult audience will be composed of 8 focus groups of 3–8 participants each, and the parent/caregiver audience will be composed of 6 focus groups of 3–8 participants each (up to N=156). Virtual focus groups will have no fewer than 3 participants and no more than 8 participants, as this is best practice for virtual groups (Abrams et al., 2015). In the event that only one participant shows up to a virtual focus group, an individual interview, where the moderator individually leads the participant through the activities outlined in the moderator guide, may be conducted.

Focus Groups:

Prior to the start of the virtual focus groups, participants will be contacted by a study coordinator with the market research recruitment vendor to ensure that the virtual platform (Zoom) being used for the virtual groups is installed and functioning properly. While many participants will be familiar with the secure Zoom platform, participants will be contacted with instructions on how to properly use the platform; some participants may be contacted by phone if follow-up help is needed. A virtual test call may be conducted by the recruitment vendor with the participant prior to the virtual focus group to ensure that participants can use the virtual Zoom platform and that it is functioning properly as previously described. This process will take no longer than 5 minutes.

We will invite up to 8 participants to each virtual focus group. If for any reason (e.g. late arrivals, operating a motor vehicle) a participant is dismissed on the day of the group the participants who are dismissed will still receive the incentive, and they will be informed that they are no longer needed to participate. Researchers will inform participants that they are not being dismissed because of anything related to their demographic profile.

To check participants into the focus groups, the moderator will have a participant check-in list provided by the market research recruitment vendor with first names, or provided pseudonyms, and unique ID numbers. The check-in list will be destroyed at the conclusion of each virtual focus group.

Focus Groups Process:

Trained moderators with experience leading qualitative studies on sensitive topics will moderate each focus group, with support from no more than one other Rescue Agency researcher for assistance and technical support. Participation in the focus group will not exceed 90 minutes for all audiences (i.e., teen, young adult, and parent/caregiver audiences). The moderator will engage participants in a discussion about their perceptions, attitudes, behaviors, and experiences in relation to cannabis use and their perception of risk using a semi-structured discussion guide (see Attachment: Teen SNT Moderator Guide; Teen EXP Moderator Guide; Young Adult Moderator Guide; Parent/Caregiver Moderator Guide). Moderators will encourage participants to respond openly and spontaneously, will inform participants that they can choose which questions to respond to, and that they may choose to not respond to questions without penalty.

All focus groups will be live streamed privately so that other non-research Rescue Agency personnel and external partners (i.e., CDPH-SAPB) can observe the discussion in real time without participating, interacting with the participants, or accessing participant data. The live stream will only be accessible to Rescue Agency personnel and external partners (i.e., CDPH-SAPB) and will not be shared with any other persons. Live streaming the focus groups is a required part of this study, therefore, to be eligible, all participants must indicate assent/consent via the assent/consent forms that they agree to the discussion being live streamed and observed by a limited number of California Department of Public Health and Rescue Agency personnel, through logging onto a virtual platform. This allows for non-research Rescue Agency personnel and external partners (i.e., CDPH) to participate in real-time observation while ensuring that no interactions between observers and participants occur. The live stream feed will be password protected, will be accessed through a secure connection by invitation only, and live stream observers will not have the capability to video or audio record independently. Observers will access the live stream in a location in which only approved personnel are present, with a closed door and computer screen out of view of any windows to prevent inadvertent sharing of any audiovisual data.

Additionally, all focus groups will be audio-recorded to ensure participants' perspective are accurately represented while allowing for the prompt removal of any identifying information prior to data analysis, thereby protecting participant confidentiality and privacy. Audio recording focus group discussions allows the research team to revisit the participant responses and capture the full depth, nuance, and context of their insights, resulting in richer and more reliable data. This process also ensures that participants' time and contributions are respected, as it allows their full perspective to be reflected in the study's findings. At the conclusion of each focus group, the audio will be transcribed and de-identified, and only the de-identified transcripts will be used for analysis to protect participant privacy and confidentiality. Audio recording of the focus groups is a required component of this study, therefore, to be eligible, all participants must indicate assent/consent to having the discussion audio-recorded via the assent/consent forms.

Focus groups will be audio-recorded but will not be video recorded, therefore

virtual focus group participants will be asked to share their audio and encouraged, but not required, to share their video, depending on their individual comfort level.

Essentially, participation in the focus group requires all participants to indicate assent/consent to live stream and audio record the discussion via the assent/consent forms. To further protect participant privacy, they will be reminded by the moderator, during the check-in, that they may also choose to use a pseudonym they are comfortable with during their participation in the focus group.

The flow of the focus groups for all three audiences (i.e., teens, young adults, and parents/caregivers) is the same with the exception of minor differences in timing and activities between audiences. This is indicated in the moderator guides (see Attachments: Teen SNT Moderator Guide; Teen EXP Moderator Guide; Young Adult Moderator Guide; Parent/Caregiver Moderator Guide) and summary and description of focus group activities below.

Summary of Focus Group Activities, Phase 1 Formative Research:

- ? Technical Check of Zoom Platform
- ? Consent Review
- ? Check-In Survey
- ? Study Introduction
- ? General Discussion
- ? Statement Survey and Fact Discussion
- ? Existing Resource Testing [Parents/Caregivers only]
- ? Preexisting Ad Testing
- ? Check Out

A description of each activity is presented below:

0. Technical Check of Zoom Platform (5 minutes)

1. Consent Review (10 minutes): Moderator will review assent/consent form with participants, allowing an opportunity for participants to ask questions and have them answered.

2. Check-In Survey (10 minutes): Will assess perspectives and behaviors related to cannabis use among teens, young adults, and parents/caregivers. It will cover topics such as cannabis use patterns, motivations, risk perceptions, mental health and lifestyle factors, and parental or social influences on attitudes and communication about cannabis (see Attachments: Teen SNT Check-In Survey; Teen EXP Check-In Survey; Young Adult Check-In Survey; Parent/Caregiver Check-In Survey).

a. Check-In Survey Procedures: The check-in survey collects brief, non-identifying information about participants' perceptions of cannabis risk and related attitudes that helps contextualize the qualitative insights gathered during the focus group discussions. The check-in survey is administered only after a participant has (i) completed the Screener Survey, (ii) been confirmed eligible, (iii) provided completed parental permission/assent or consent, and (iv) been scheduled for a focus group.

Once participants complete the screener survey and are determined eligible,

each participant receives a unique participant ID, and all check-in survey responses are stored using this ID only. No check-in survey data are ever linked to names or other identifying information (e.g., names, email, or phone numbers). Participant names and contact information are collected only voluntarily (i.e., if participants provide this information via the parental permission or consent forms to be recontacted for future study activities) which are stored separately and used solely for recontact purposes. If a participant completes the check-in survey but does not attend the focus group or withdraws before participation, their check-in survey data are deleted and not included in analysis. Only de-identified information from participants who complete the focus group is retained. These procedures ensure that check-in survey data are used solely to support Phase 1 activities while maintaining strict confidentiality and respecting voluntary participation.

3. Study Introduction (5 minutes): The moderator will explain the study purpose and provide general ground rules for participation in the focus group.

4. General Discussion (30–40 minutes): The moderator will guide the participants through a general semi-structured discussion about their experiences, attitudes, and beliefs around cannabis use (see Attachments: Teen SNT Moderator Guide; Teen EXP Moderator Guide; Young Adult Moderator Guide; Parent/Caregiver Moderator Guide).

5. Statement Survey and Fact Discussion (20–25 minutes): The moderator will ask participants to complete a brief survey on a series of factual statements to determine if they have seen this information before, if they believe it, and how motivating the statements are to affect behaviors related to cannabis use. The moderator will then discuss these statements with participants (see Attachments: Teen SNT Statement Survey; Teen EXP Statement Survey; Young Adult Statement Survey; Parent/Caregiver Statement Survey).

6. Existing Resource Testing [Parents/Caregivers only] (10 minutes): Parents and caregivers will review an existing educational website that provides evidence-based tips and resources to help them talk with their teens about cannabis use and its associated risks, and provide qualitative feedback, through discussion, about its effectiveness.

7. Preexisting Ad Testing (20–25 minutes): The moderator will ask participants to provide their feedback on video advertisements and how well they resonate with all audiences. Each audience will be shown different videos (see Attachments: Stimuli [by audience]) to test which styles, tones and approaches work best.

8. Check Out (5 minutes): The moderator thanks the participants for their time and answers any questions the participants may have.

Phase 1 - Data Collection Procedures

? Screener Surveys: The Screener Survey is a brief questionnaire used to

determine eligibility for participation in the study and to ensure appropriate demographic representation across focus groups for each audience. For the teen audience, specific survey questions are asked to parents/guardians of teens to determine their child's eligibility in the study, if the child is eligible based on the parent/guardian responses, permission is then obtained from the parents/guardians to send the online "Teen Screener Survey" to their child. Young adults and parents/caregiver audiences receive a link to respond to the relevant screener survey directly from the recruitment vendor.

The screener is completed before any study procedures occur and only after individuals have reviewed introductory information describing the purpose of the screener, the types of questions included, and how responses will be used. No personal identifiers (e.g., full name, phone number) are collected as part of the Screener Survey.

The screener includes eligibility-determining questions (e.g., age range, caregiver status, cannabis communication experience) as well as demographic items such as race/ethnicity, educational attainment, and ZIP code. These demographic variables are collected because they are necessary for recruiting a demographically appropriate, diverse, and equitable sample aligned with CDPH's statewide public health and health equity priorities. Race/ethnicity and education are associated with youth cannabis-related beliefs, parental communication patterns, and differential exposure to substance-use risk environments; therefore, collecting these variables at screening supports quota-based sampling, a widely accepted method in public health research for reducing sampling bias and ensuring inclusion of historically underrepresented groups (AAPOR, 2020; DeLeeuw et al., 2020; NASEM, 2017). These demographic fields do not independently determine eligibility but are essential for distributing participants into groups that reflect the populations most impacted by youth cannabis prevention efforts. ZIP code is collected instead of "city" or "town" since it provides sufficient geographic information to assess regional representation while minimizing identifiability, particularly for participants living in small or rural communities. ZIP code data are standard in behavioral health recruitment due to their relevance to local cannabis exposure, retail density, and community risk environments (NASEM, 2017). Using ZIP code adheres to the ethical principle of collecting only the "minimum necessary" information while still enabling representative sampling (CIOMS, 2016; U.S. Census Bureau, 2022).

Individuals who screen ineligible or choose not to continue will have all screener data deleted and not retained. For those who screen eligible and subsequently complete the signed consent or assent/parental permission process, relevant screener variables are retained in a fully de-identified format using only a unique participant ID. This approach ensures that only the information necessary to support valid sampling and study implementation is collected and that all demographic screening information is handled in a manner consistent with confidentiality protections and human-subjects research standards.

Therefore, we request IRB Board approval to retain select screener responses, and all participants will be informed that their screener responses can be retained before starting the screener surveys if they indicate parental permission/assent or consent in the assent/consent forms. Retaining a minimal subset of screener responses for individuals who are eligible and

providing full consent is considered acceptable and often preferred in behavioral research when the retention plan is clearly disclosed and approved by the IRB Board. Ethical guidelines note that screening data may be stored or analyzed when parental permission and/or assent/consent forms include information about data use and confidentiality protections (CIOMS, 2016), and institutional IRB standards similarly state that retention is permissible when explicitly described in the protocol (University of California, Berkeley CPHS, n.d.). Research literature also demonstrates that analyzing de-identified screening variables can improve sample representativeness, reduce selection bias, and support appropriate recruitment and segmentation (Baysinger et al., 2023). Retaining these limited, de-identified data also prevents duplicate burden on participants, enables accurate description of the enrolled sample, reduces social desirability bias, and ensures that demographic criteria central to study validity are collected only once (DeLeeuw et al., 2020; Tourangeau et al., 2012). Screener data for all non-participants will be deleted, ensuring that de-identified data is retained only for consented participants who complete all study activities.

Overall, demographic information (age, education, race/ethnicity, gender, and ZIP code) will be used to monitor enrollment and ensure that the final sample reflects statewide demographic and regional representation quotas.

Use of Screener Demographic Information for Sample Composition and Quota Management

To ensure that the study sample is demographically appropriate, equitable, and reflective of the populations most impacted by youth cannabis prevention efforts in California, several key demographic variables—including race/ethnicity, educational attainment, and ZIP code—are collected as part of the Screener Survey. These variables are not initially used as exclusion criteria. However, demographic quotas are set for each phase of research, as shown in Table 1 below. These recruitment goals are informed by publicly available population data. As a general guideline, the study aims for the final sample to fall within approximately $\pm 5\%$ of statewide benchmarks across key demographic variables. Recruitment staff conduct periodic quota reviews at predefined recruitment checkpoints (e.g., approximately $n=15$, $n=30$, $n=45$, $n=60$) to assess progress toward these targets. If the recruitment goal for a particular demographic subgroup has been met at one of these checkpoints, additional individuals from that subgroup are no longer recruited. At that point, these variables may be used as exclusion criteria. This approach ensures we are able to implement the study's sampling plan and construct balanced focus group compositions.

Rationale for Collecting Demographic Variables During Screening: Collecting demographic data at the screening stage is necessary because sample-balancing decisions must be made before participants are formally enrolled, consented, and scheduled into groups. The recruitment vendor reviews screener responses in real time to:

1. Monitor demographic distribution of individuals expressing interest in the study;
2. Ensure that no subgroup is disproportionately over- or under-represented relative to statewide youth and caregiver demographics;
3. Prioritize inclusion of historically marginalized groups who may have

distinct cannabis-related perceptions, communication patterns, or exposure contexts; and

4. Assign eligible participants to focus groups in a way that ensures each session includes a range of experiences and perspectives aligned with CDPH health-equity goals.

These demographic variables are necessary to operationalize the study's quota-based sampling plan, which is a standard and widely accepted method in public health and mixed-methods research for ensuring adequate representation and for preventing biased or skewed samples. The specific quotas used for each segment of this study are presented in Table 1 below and guide the distribution of eligible participants across groups.

Table 1. Quota-based sampling plan

Demographic and Psychosocial

Quotas

Teens N=60-72

Young Adults N=40-48

Parents/Caregivers N=30-36

Ideal n [min] Ideal % [min] Ideal n [min] Ideal % [min] Ideal n [min] Ideal % [min]

Location Northern California 3 5.0% 2 5.0% 2 5.0%

Greater Sacramento/

Bay Area 9 15.0% 6 15.0% 5 15.0%

San Joaquin Valley 5 8.0% 3 8.0% 3 8.0%

Southern California 30 50.0% 20 50.0% 15 50.0%

Race/

Ethnicity Non-Hispanic White 21 35.0% 14 35.0% 11 35.0%

Hispanic or Latino 24 40.0% 16 40.0% 15 50.0%

Black or African American 6 10.0% 4 10.0% 3 10.0%

Asian 3 5.0% 2 5.0% 1 5.0%

American Indian or Alaska Native N/A N/A N/A N/A N/A N/A

Gender

Female 24 40.0% 16 40.0% 12 40.0%

Male 24 40.0% 16 40.0% 12 40.0%

Another gender identity 3 5.0% 2 5.0% 1 3.0%

Sexual Orientation LGBTQIA+ 5 8.0% 3 8.0% 2 5.0%

Spanish Fluency Speak Spanish [parents/caregivers only] N/A N/A N/A N/A
12 33%

User Status Susceptible Non-Trier [teens only] 30 50.0% N/A N/A N/A N/A

Experimenter [teens and YAs only] 30 50.0% 40 100% N/A N/A

ACEs Experienced 2 or more ACEs SNT: 30 SNT: 100% 30 75% 8 25%

EXP: 23 EXP: 75%

How Demographic Information Is Used to Assign Participants to Groups: Demographic variables (e.g., race/ethnicity, education, ZIP code) are used by the recruitment vendor to assign eligible participants to specific focus groups so that each group reflects the desired diversity targets specified in the quota plan. This process occurs prior to scheduling and prior to the distribution of consent materials, ensuring that:

? Each group contains a balanced mix of participant backgrounds

? Representation goals are met without excluding individuals after consent;

and

? No participant is displaced or removed due to oversampling of one demographic subgroup.

Participants are never informed of the quota criteria or how their demographic characteristics influence group placement.

Why These Variables Cannot Be Collected in the Check-In Survey: The Check-In Survey occurs after the participant has:

1. completed the screener and deemed eligible,
2. been scheduled for a focus group, and
3. received and returned consent or assent/parental permission forms.

At this stage, demographic information cannot be used for group assignment because doing so would require removing or reassigning individuals who have already consented—an ethically inappropriate practice that could undermine participant autonomy and disrupt study flow. Instead, the Check-In Survey is limited to measures used solely for analysis (e.g., perceptions of cannabis risk, age-of-initiation beliefs). All demographic-based sampling decisions must therefore be completed at screening.

Data Protection and Retention:

? Demographic screener data are retained only for individuals who complete parental permission and/or consent/assent and participate.

? Screener data are stored in a fully de-identified form, labeled only by unique participant ID.

? Screener data from individuals who do not participate (ineligible or decline) are permanently deleted and never included in analysis.

? Check-In Surveys: The check-in survey is administered only after participants have completed the screener survey, been confirmed eligible, and submitted a signed consent or assent and parental permission form.

Participants receive a link to the check-in survey when they are scheduled for their focus group session and are instructed to complete it either prior to the session or during early login. The check-in survey collects non-identifying information about participants' perceptions of cannabis risk, age of initiation, and contextual attitudes that help inform the interpretation of qualitative findings.

All check-in survey responses are stored using each participant's unique participant ID, assigned at enrollment. No names or other direct identifying information are collected through the check-in survey, and the participant ID key is stored separately from analytic data in a secure, access-restricted folder.

If a participant completes the check-in survey but does not attend the focus group or withdraws before or during participation, their check-in survey responses are deleted and not retained. Only participants who complete the focus group session will have their de-identified check-in survey data included in analysis. Check-in survey results will be analyzed descriptively and integrated with statement survey findings and thematic codes from transcripts to triangulate insights. All findings will be reported in aggregate to ensure no individual participant can be identified.

? De-identified focus group transcripts: Audio recordings of each focus group will be transcribed verbatim by trained Rescue Agency researchers or a transcription vendor under confidentiality agreement. Immediately after transcription, any accidental identifiers mentioned during the group (e.g., names, school names, specific locations) will be redacted. Each transcript is labeled only with the participant IDs assigned at enrollment; no names or

direct identifiers appear in the transcripts. Transcripts, once de-identified, are stored in a secure research folder accessible only to Rescue Agency researchers and are analyzed using thematic analysis procedures. Transcripts will not be shared outside the Rescue Agency research team and external partners (i.e., CDPH), and all reporting will be aggregated to ensure no individual participant's comments can be traced back to them.

? Statement Survey: During each focus group, participants complete a brief statement survey assessing their reactions to cannabis-related statements and messages. Participants access the survey using a secure link during their scheduled focus group. The survey does not collect names or direct identifiers; instead, responses are tagged with each participant's unique participant ID for analytic integration. Statement survey responses will be stored separately from parental permission and/or assent/consent forms or scheduling information and will only be linked to other de-identified data sources (e.g., check-in survey and transcript excerpts) via the unique participant ID. Survey results will be analyzed using descriptive statistics and will be combined with qualitative themes from transcripts to triangulate findings. All reported results will be presented in aggregate and will not contain any potentially identifying detail.

Together, these procedures ensure that all data used for analysis—whether from the screener survey, check-in survey, focus group transcripts, or statement survey—are fully de-identified and linked only through a unique participant ID. Voluntarily provided identifying information is stored separately, used exclusively for operational purposes such as invites to future research activities, and is not merged with analytic data. This approach maintains confidentiality, aligns with standards for minimal-risk behavioral research, and supports valid mixed-methods analysis without compromising participant privacy.

Ultimately, insights from Phase 1: Formative Research will be used to conceptualize, develop, implement, and market test an age-specific, developmentally appropriate, and scientifically accurate media and social marketing campaign to educate youth, young adults, and parents/caregivers on the risks and consequences of cannabis use while influencing youth attitudes, social norms, and perceptions of cannabis.

Participant Retention and Re-engagement

Adult participants (i.e., young adults, parents/caregivers) and parents/guardians of teen participants will have the opportunity to provide their contact information if they wish to be contacted for future study activities through the parental permission and consent forms. This section of the parental permission and consent forms will specify that contact information (e.g., email and/or phone number) will be used solely for research contact purposes, that providing contact information is entirely optional, that there is no penalty for choosing not to provide contact information, and that they can opt to remove their contact information from this list at any time. In the case of teen participants, their parents/guardians may be contacted with an invitation for their teen to participate in future activities. If adult participants or parents/guardians of teen participants opt-in to be contacted for participation in future activities of the study they must

provide their email address and/or phone number via the parental permission or consent forms, or select the statement 'I prefer not to be contacted for future projects' - any participants who select this statement will not be contacted. Participants' contact information will be stored in a password-protected server only accessible to Rescue Agency researchers, separate from any participant data (e.g., survey responses, transcripts).

In any follow-up communication, research staff will contact adult participants and parents/guardians of teen participants by sending an invitation email or text message that will provide details about upcoming research activities, research staff contact information, and a unique survey link to the appropriate screener survey for the upcoming research activity (i.e., Phase 2: Brand and Creative Message Testing or Phase 3: Red Flag Testing). To participate, interested individuals must complete the screener survey for the new study activity to confirm eligibility, and must provide parental permission and informed assent or consent again. Participants will have the opportunity to ask any questions they have before participating, and will be informed that their participation in any additional study activity is entirely voluntary.

Phase 2 - Brand & Creative Message Testing, Focus Groups

At the conclusion of Phase 1, the insights gathered will be used to produce creative educational materials designed to speak to the teen, young adult, and parent/caregiver audiences about the risks associated with youth cannabis use; these materials will then be tested through focus groups in Phase 2 of the study. The purpose of the brand and creative message testing focus groups is to assess reactions and receptivity to these educational materials, in order to guide their refinement and increase their effectiveness. As the final creative concepts and research materials rely on the findings from Phase 1, we have included an outline of the likely activities. However, the final brand and creative messages for testing and corresponding research materials for Phase 2 will be submitted as an amendment at the end of Phase 1.

Similar to Phase 1, Phase 2 proposes 18 focus groups with up to 8 and no less than 3 participants each across three audiences (i.e., teens, young adults, and parents/caregivers) (up to N=126). All procedures (e.g., screening, recruitment, assent/consent, and data collection) will be the same as those described for Phase 1. Focus group activities for Phase 2 will include a mix of check-in surveys, semi-structured discussions, and a brief quantitative survey to assess the creative messages' effectiveness and likelihood to stimulate behavior change. Participants will provide feedback on message clarity and understanding, perceptions of style and tone, reactions to the message, and whether they connect with the message values that will aim to encourage health promotion messages regarding youth cannabis use and prevention. Ultimately, this information will be utilized to inform the educational messaging strategy for a youth cannabis prevention public health campaign.

Summary of Focus Group Activities, Phase 2:
? Check-In Survey

- ? Study Introduction
- ? General Discussion
- ? Brand and Creative Message Testing
- ? Check Out

A description of each activity is presented below:

1. Check-In Survey: Will assess perspectives and behaviors related to cannabis use among teens, young adults, and parents/caregivers. It will cover topics such as cannabis use patterns, motivations, risk perceptions, mental health and lifestyle factors, and parental or social influences on attitudes and communication about cannabis.
2. Study Introduction: The moderator will explain the study purpose and provide general instructions for participation in the focus group. Similar to Phase 1, participants will be asked to provide written parental permission and/or assent/consent to live stream and audio record the discussion; agreeing to the live stream and audio recording is required for participation.
3. General Discussion: Participants will engage in a general discussion about topics related to perceptions and current knowledge of youth cannabis use, the risks associated with frequent use or early initiation, and other items of interest that emerged as a result of findings from the formative research phase.
4. Brand and Creative Message Testing: This activity is intended to provide insight into the most promising creative messages for the statewide education campaign and guide refinement of the creative strategy. Sets of preliminary creative messages designed to tap into the unique values and interests of the audience will be tested. Creative messages may include video storyboards, which are sketches of videos that focus on a health promotion message, and preexisting ads. For each creative message, respondents will first respond to a series of Likert-scale statements to preliminarily assess ad effectiveness, which will be followed with a qualitative group discussion. The order of the presented creative messages will be randomized between focus groups to minimize order effects. Additional qualitative discussion will assess participants' preferences for and opinions of each message, emotional reactions and associations with the message, as well as intentions to engage with the message.
5. Check Out: The moderator thanks the participants for their time and answers any questions the participants may have.

Phase 2 - Data Collection Procedures

Specific information about data collection procedures for Phase 2: Brand and Creative Message Testing will be submitted for approval through an amendment at the conclusion of Phase 1 (e.g., Summer - Fall 2026).

Phase 3 - Red Flag Testing, Campaign Materials

Following campaign production, Rescue Agency will conduct Red Flag Testing to identify and mitigate any unanticipated interpretations or reactions prior

to public launch. This quality assurance step will consist of up to 9 focus groups with up to 8 and no less than 3 participants each across the three target audiences (up to N=54) to review the finalized campaign assets and confirm that messaging and visuals are being interpreted as intended. Findings from this testing will inform any final creative refinements before campaign launch, providing one last validation point to ensure the campaign resonates positively with all target audiences. This phase builds upon the earlier Phase 1 and Phase 2 research activities that informed campaign development, serving as a final safeguard before go-live. Red Flag Testing may be conducted virtually, through focus group format, based on participant availability. Participants who previously opted in to participate in future study activities will be re-contacted for this phase (see page 12, "Participant Retention and Re-engageent"). All research protocols (e.g., recruitment, assent/consent, data safeguards) established in earlier phases will continue to be followed to ensure participant privacy, data security, and ethical compliance. As the final produced campaign materials tested in Phase 3 will rely on the findings from Phase 2, we have included an outline of the likely activities. However, the final campaign materials for testing and corresponding research materials for Phase 3 will be submitted as an amendment at the end of Phase 2.

Summary of Focus Group Activities, Phase 3:

- ? Study Introduction
- ? General Discussion
- ? Campaign Materials Testing
- ? Check Out

A description of each activity is presented below:

1. Study Introduction: The moderator will provide general instructions for participation in the focus group. Similar to Phase 1 and 2, participants will be asked to provide written parental permission and/or assent/consent to live stream and audio record the discussion; agreeing to the live stream and audio recording is required for participation.
2. General Discussion: Participants will engage in a general discussion about topics related to perceptions and current knowledge of youth cannabis use, the risks associated with frequent use or early initiation, and other items of interest that emerged as a result of findings during the formative research phase.
3. Campaign Materials Testing: This activity is designed to gather feedback on finalized campaign materials for the statewide education campaign to confirm that they effectively convey their intended messages and do not produce any unanticipated interpretations or reactions. Participants will review completed creative materials, such as video storyboards, finalized ads, or other campaign components, and provide their reactions and insights. For each material, participants will respond to a series of Likert-scale statements to assess aspects such as clarity, relevance, and overall effectiveness, followed by a qualitative group discussion. These discussions will explore participants' perceptions, emotional responses, and any unanticipated interpretations or reactions. The order of materials will be

randomized across groups to minimize order effects and ensure balanced feedback.

4. Check Out: The moderator thanks the participants for their time and answers any questions the participants may have.

Phase 3 - Data Collection Procedures

Specific information about data collection procedures for Phase 3: Red Flag Testing will be submitted for approval through an amendment at the conclusion of Phase 2 (e.g., Spring - Summer 2027).

State Data and Data Sharing with External Partners

No state data will be used for this project, all data will be collected from newly recruited participants - see page 22 for recruitment procedures and page 26 for audience inclusion criteria.

Additionally, de-identified data (e.g., contact details, names, and other unique identifiers will be removed so that no one can reasonably trace the data back to a specific person) will be shared with the California Department of Public Health (CDPH) who may retain the data beyond three years.

External partners from California Department of Public Health (CDPH) will not interact directly with participants, will only observe focus groups through the live stream, and will not have access to any linked data or be involved in data management, processing, analysis, or reporting. All data shared with CDPH will be cleaned and de-identified by Rescue Agency.

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.

CDPH IRB Cannabis Confidentiality Agreements.docx	Certificate of Confidentiality
CAPH-SAPB_IRB Letter Information Privacy and Security.pdf	Data Security Letter
[04_29] CDPH Cannabis_Teen EXP Moderator Guide.docx	Instruments
[04_29] CDPH Cannabis_Teen SNT & EXP Screener Survey.docx	Instruments
[04_29] CDPH Cannabis_Teen SNT Moderator Guide.docx	Instruments
[04_29] CDPH Cannabis_YA Moderator Guide.docx	Instruments
[04_29] CDPH Cannabis_YA Screener Survey.docx	Instruments
CDPH Cannabis_Parents_Caregivers Check-In Survey_Spanish.docx	Instruments
CDPH Cannabis_Parents_Caregivers Moderator Guide.docx	Instruments
CDPH Cannabis_Parents_Caregivers Moderator Guide_Spanish.docx	Instruments

CDPH Cannabis_Parents_Caregivers Statement Survey_Spanish.docx	Instruments
CDPH Cannabis_Teen EXP Moderator Guide.docx	Instruments
CDPH Cannabis_Teen SNT Moderator Guide.docx	Instruments
CDPH Cannabis_YA Moderator Guide.docx	Instruments
Stimuli - A Voice in the Noise.mp4	Instruments
Stimuli - Dr. Chris, Pharm D.mp4	Instruments
Stimuli - Pete Davidson Interview.mp4	Instruments
Stimuli - Stress Loop.mp4	Instruments
Stimuli - Tea on THC-Teen.mp4	Instruments
Stimuli - THC-Parent Talking Tips.mp4	Instruments
Stimuli - Unfazed_ Quick Social Trend.mp4	Instruments
Stimuli - Unfazed_ Storytelling.mp4	Instruments
Stimuli - We Have to Talk About Weed.mp4	Instruments
CDPH Cannabis_Recruitment Email Templates_12.12.docx	Misc/Other
CDPH Cannabis_Recruitment Phone Script Templates_12.12.docx	Misc/Other
CDPH-SAPB IRB Reviewer - Feedback [12_15].docx	Misc/Other
CDPH-SAPB IRB Reviewer - Feedback .docx	Misc/Other
CDPH-SAPB Cannabis Protocol_2025-178 [12_12].docx	Protocol
CDPH-SAPB Cannabis Protocol_2025-178 [2_5_26].docx	Protocol
CDPH Cannabis_Parents_Caregivers Check-In Survey.docx	Questionnaires
CDPH Cannabis_Parents_Caregivers Statement Survey.docx	Questionnaires
CDPH Cannabis_Teen EXP Check-In Survey.docx	Questionnaires
CDPH Cannabis_Teen EXP Statement Survey.docx	Questionnaires
CDPH Cannabis_Teen SNT Check-In Survey.docx	Questionnaires
CDPH Cannabis_Teen SNT Statement Survey.docx	Questionnaires
CDPH Cannabis_YA Check-In Survey.docx	Questionnaires
CDPH Cannabis_YA Statement Survey.docx	Questionnaires
CDPH Cannabis_Parents_Caregivers Screener Survey_Spanish.docx	Recruitment (non-English)
CDPH Cannabis_Parents_Caregivers Screener Survey.docx	Recruitment Materials
CDPH Cannabis_Teen SNT & EXP Screener Survey.docx	Recruitment Materials
CDPH Cannabis_YA Screener Survey.docx	Recruitment Materials
CPHS Bill of Rights Non-Medical - English.pdf	Recruitment Materials

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.).

As detailed in the parental permission and assent/consent forms, focus groups will be audio recorded and live streamed, and parents/guardians and/or participants must indicate that they agree to the discussion being recorded and live streamed on the parental permission and assent/consent form. All interested participants must read and return the completed parental permission and/or assent/consent form to the research team indicating they agree to being audio recorded and agree to the live stream before they are invited to participate in a focus group. If any participants in the focus group indicate that they do not want the discussion to be audio recorded or be included in the live stream, they can choose to end their participation in the study without penalty and will receive the incentive for joining the group.

Focus group discussions will be recorded using the secure webinar platform. At the conclusion of the focus group, the audio file will be transferred to Rescue Agency's password protected file storage system that is only accessible to Rescue Agency research staff within 1 hour of the conclusion of the focus group. The audio files from Phase 1, Phase 2, and Phase 3 will be transcribed so that only written, and de-identified, documentation of data is available. All transcribers will sign a confidentiality agreement (see Attachment: Confidentiality Agreements). After transcription, all audio files will be erased (no later than 1 year after the focus group). The transcriptions will be reviewed and any identifiable information will be removed. The de-identified transcripts will then be used for subsequent qualitative data analysis.

Additionally, de-identified data (e.g., contact details, names, and other unique identifiers will be removed so that no one can reasonably trace the data back to a specific person) will be shared with the California Department of Public Health (CDPH) who may retain the data beyond three years.

External partners from California Department of Public Health (CDPH) will not interact directly with participants, will only observe focus groups through the live stream, and will not have access to any linked data or be involved in data management, processing, analysis, or reporting. All data shared with CDPH will be cleaned and de-identified by Rescue Agency.

Audio Recording and Live Stream - Role-Specific Confidentiality Agreements and Access Control Procedures

Rescue Agency employs three role-specific confidentiality agreements (i.e., Rescue Agency non-research staff observers, external partner observers, and

transcribers) to ensure that every individual who observes the live stream or transcribes audio recordings is governed by standardized confidentiality protections. These agreements operationalize the principles of data minimization and the role-appropriate access control recommended in human-subjects research oversight. Each agreement must be signed and returned to Rescue Agency before access to focus group live streams is granted to observers and before or audio files are shared for transcription. All signed agreements are stored in secure, access-restricted, project files. These agreements establish standardized confidentiality expectations aligned with IRB oversight and apply to Rescue Agency non-research staff, external partners, and professional transcription personnel.

Rescue Agency Observers (non-research staff): Who are not part of the core research team (e.g., campaign strategy or creative staff) may observe focus groups solely to inform campaign strategy and development. These employees do not interact with participants, analyze data, or access recordings or transcripts. To observe the live stream, non-research Rescue Agency staff must:

Sign the Employee Confidentiality Agreement prior to observation

Attend in a camera-off, audio-off, observer-only capacity

Understand that they are prohibited from recording, note-taking with identifiers, or discussing participant content outside the project team

Rescue Agency observers will only view the live stream; they will not receive copies of, or be granted access to, any research data.

External Partner Observers (CDPH staff): CDPH personnel may observe sessions exclusively for oversight and program-development purposes, but will not collect or analyze any participant data. Before any access to the live stream is granted, these individuals must:

Sign the External Partner Confidentiality Agreement prior to observation

Attend in a camera-off, audio-off, observer-only capacity

Understand that they are prohibited from recording, note-taking with identifiers, or discussing participant content outside the project team

Follow all IRB-approved confidentiality procedures established by CDPH (see Attachment: CDPH Data Security Letter) during observation

External partner observers will only view the live stream; they will not receive copies of, or be granted access to, any research data. Observation links and access are not provided until confidentiality agreements are signed and stored by Rescue Agency.

Transcription Personnel: Transcription is typically conducted by Rescue Agency research staff already bound by IRB-approved confidentiality provisions. If a professional transcription vendor is engaged, the vendor signs the Transcription Confidentiality Agreement before receiving any study materials. Only audio files are provided to transcription vendors; they do not receive names, contact data, or participant-specific metadata. Upon completion, audio and transcribed files are securely transferred back to the Rescue Agency research team and stored or deleted in accordance with secure data-handling protocols. Any incidental identifiers spoken during the session are redacted before analysis.

These project-specific agreements supplement, and do not replace, existing confidentiality frameworks, including Rescue Agency's training and external

vendor certifications to establish a uniform baseline of expectations tailored to:

The involvement of adolescents in the research

The sensitive domain of substance use behaviors and attitudes

Live stream exposure to potentially identifiable verbal disclosures

All agreements are securely stored in project files. Access permissions are tracked and granted only by Rescue Agency research staff. Any breach will result in immediate revocation of access to live streams and required reporting to the IRB. These layered protections ensure that all individuals exposed to study information adhere to standardized, IRB-approved confidentiality rules, reducing risk of unauthorized disclosure to the lowest practicable level.

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.

English speaking teens and young adults, and English and Spanish speaking parents/caregivers will be recruited for participation in Phase 1, Phase 2, and Phase 3 of this study. Since the focus of this project is to understand knowledge, attitudes, beliefs, and perceptions about youth cannabis use in California, teen and young adult participants will be recruited if they are currently living in California, fall within the established age groups for each audience, and are susceptible non-triers of cannabis or previous/current users of cannabis. Similarly, parents/caregivers will be recruited if they are living in California, fall within the established age group, have a child between the age of 11–17, and report not having frequent conversations about cannabis with their child. Recruitment will include all genders, ethnicities, and regions, aiming to mirror the regional and demographic breakdown of individuals in California (see Table 1).

We are requesting the following:

Phase 1: Formative Research (N=156)

Formative research focus group data will be collected for up to N=156 participants.

Teen Audience (up to n=72)

- 13–17 years old
- 12 Focus Groups with up to 8 and no less than 3 participants

Young Adult Audience (up to n=48)

- 18–20 years old
- 8 Focus Groups with up to 8 and no less than 3 participants

Parents/Caregivers Audience (up to n=36)

- 30–55 years old
- 6 Focus Groups with up to 8 and no less than 3 participants

Requests for approval for future phases will be submitted at a future date, but those phases are briefly described below:

Phase 2: Brand and Creative Message Testing (N=126)

Brand and creative message testing focus group data will be collected for up to N=126 participants.

Teen Audience (up to n=48)

- 13–17 years old
- 8 Focus Groups with up to 8 and no less than 3 participants

Young Adult Audience (up to n=42)

- 18–20 years old
- 7 Focus Groups with up to 8 and no less than 3 participants

Parents/Caregivers Audience (up to n=36)

- 30–55 years old
- 6 Focus Groups with up to 8 and no less than 3 participants

Phase 3: Red Flag Testing (N=54)

Final campaign materials focus group data will be collected for up to N=54 participants.

Teen Audience (up to n=24)

- 13–17 years old
- 4 Focus Groups with up to 8 and no less than 3 participants

Young Adult Audience (up to n=18)

- 18–20 years old
- 3 Focus Groups with up to 8 and no less than 3 participants

Parents/Caregivers Audience (up to n=12)

- 30–55 years old
- 2 Focus Groups with up to 8 and no less than 3 participants

RATIONALE

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

Youth cannabis use in California is a priority area for messaging as early initiation of cannabis use can produce more longer-term neurological impacts and negative health outcomes (Batalla et al., 2013). To develop a culturally and linguistically appropriate media and social marketing campaign that provides scientifically accurate education and builds credibility and trust among priority audiences, there is a need to understand the teen, young adult and parents/caregivers populations. Therefore, this study plans to leverage data from individuals 13–55 years of age to do so.

Teen Audience (ages 13–17)

According to the National Survey on Drug Use and Health, cannabis was the most used illicit drug among adolescents ages 12–17 (2021). In fact, about 6% of youth reported using cannabis before age 13 (Underwood et al., 2020) which may predict cannabis dependence later in life. Evidence shows that youth who start using cannabis before age 15 are more likely to develop symptoms of drug abuse (Rioux et al., 2018). This may be influenced by the fact that the earlier youth start using, the more likely they are to be exposed to more cannabis throughout adolescence and therefore are more prone to cannabis related disorders during adulthood (Hawke et al., 2020). This has significant implications for prevention strategies and delaying initial use of cannabis among teens by focusing on the health consequences of using. Therefore, this audience will be studied to determine how to motivate teens to never try or quit using cannabis as well as what type of cannabis use prevention and cessation communication resonates best with this age group.

Young Adult Audience (ages 18–20)

A recent study shows that early onset of cannabis use during early adolescence and increased use throughout may hinder successful transition into young adulthood by impacting educational and occupational achievement (Thompson et al., 2019). Persistent cannabis use in adolescence is a threat to long-term health and behavioral outcomes. A previous study showed that adolescents who reported using cannabis to get through the day may be at risk for continued use and misuse of substances, including cannabis into adulthood (Patrick et al., 2011). This suggests the use of cannabis to self-medicate may increase chances of developing cannabis use disorder. Data shows that past year cannabis use remains at an all-time high among young adults with a 9% increase from 2014 to 2019 (NIDA, 2020). As young adults often experiment with cannabis and other drugs during college years, they become resistant to most drug-free campaigns and rely on their own experiences to guide their decision making. In fact, recent substance use programming has revealed that young people are most receptive to harm reduction approaches when they are informed by youth experiences (Jenkins et al., 2017). Therefore speaking with this audience segment is essential to understand what motivates young adults to reduce or avoid using cannabis and explore how transitional periods (from

adolescence into young adulthood) impact cannabis use and perception.

Parents/Caregivers (ages 30–55)

Evidence shows that parents/caregivers can help their adolescent children delay patterns of cannabis use by clearly communicating expectations and setting limits around misuse and abuse of substances (Miller et al., 2017). Parents and caregivers may be particularly influential in changing adolescent behavior when provided with information pertinent to their interpersonal relationship. In fact, research shows that building established trust between parents and their children can prevent risky behaviors for youth, including substance use (Miller et al., 2017). Non-parent adult caregivers of children ages 11–17 may also impact a youth's decision to start using cannabis at a young age. Evidence shows that presence of role models and adults who use cannabis was a contributing factor in initiation of use by youth due to modeling behavior within the immediate environment (Manu et al., 2020). Therefore, studying this audience segment is crucial to determine how to encourage parents and caregivers to play a positive role in preventing youth cannabis use.

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.

This study uses Market Research Panel recruitment - in which individuals who have previously agreed to be contacted for research purposes are identified and contacted by vetted third-party recruitment vendors to assess their eligibility and willingness to participate in the study. Individuals under age 18 will never be contacted directly. For the teen audience, parents or legal guardians will always be the initial point of contact, and no teen will receive a screener link or study communication until their parent/guardian has provided permission, and the young adult and parent/caregiver audience will receive direct outreach from the Market Research Panel.

The Rescue Agency research team does not receive any participant contact information during recruitment or screening. Recruitment will take place across California and will be overseen by Rescue Agency, and the primary/principal mode of recruitment will be market research recruitment panels, conducted by one or more vetted professional market research recruitment vendors who have extensive experience recruiting youth and adult populations. Rescue Agency will support recruitment or coordination as needed.

Recruitment via Market Research Panel – The recruitment vendor will draw from its own existing database of individuals interested in research participation who have voluntarily signed up to participate in research. Recruitment vendors typically have basic demographic information of participants, including sex, age, and languages spoken. As the list of panelists is proprietary to the recruitment vendor, contact information (e.g., email addresses, phone numbers) for their panel members will never be provided to the Rescue Agency research team. For teen participants ages 13–17, the vendor will contact only their parents/guardians. Parents/guardians will receive the study introduction and will be asked to grant permission for their teen to complete the teen-specific screener survey. Teens will only receive a screener survey link after their parent/guardian completes the parent-facing eligibility screener and provides permission for their child to be contacted. Young adult and parent/caregiver participants will be contacted exclusively by the contracted recruitment vendor using the communication method (e.g., email, phone call) each panel member has previously opted into as part of their existing research panel membership. The Rescue Agency research team will not receive or store any participant contact information at any stage of recruitment or screening. Mode of Contact: The recruitment vendor may contact prospective participants by email or phone, depending on the participant's stated preference on file with the vendor and the vendor's standard recruitment

procedures. The vendor will administer the screener survey either electronically or by phone using identical question content across modes. Email Contact: Most participants will be contacted via email using IRB-approved invitation language that contains a link to the online screener survey. Parents/caregivers, teens (through parental permission), and young adults will complete the appropriate version of the screener survey electronically.

Phone Contact: Phone outreach may be used when (1) a participant has indicated a preference for phone communication, or (2) the vendor follows standard practice of making a phone follow-up after nonresponse to email. Phone screeners use the same question wording as the electronic versions. The teen screener is administered in two stages: a brief parent/guardian phone screener followed, if permitted by the parent/guardian, by a teen online screener survey.

Contact Attempt Limits: To minimize participant burden and respect communication preferences, the recruitment vendor will follow a restricted contact schedule:

Email invitations: Up to three (3) email attempts, spaced at least 24 hours apart.

Phone outreach: If used, up to two (2) phone attempts total, with only one (1) voicemail left.

If no response is received after the maximum number of attempts, no further contact will be made regarding this study. Individuals who do not respond or decline will not be re-contacted to participate in this study.

Privacy Protections: All initial outreach, follow-up attempts, and screener survey administration are conducted by the vendor within their secure participant-management system. Rescue Agency receives only de-identified eligibility outcomes; no names, phone numbers, email addresses, or other personal contact information are shared with or accessible to the research team at the recruitment phase.

Protection for minors during recruitment:

Parents/guardians are always the first point of contact for any participant under age 18.

Parents must complete a parent-facing screener before the teen can be contacted.

Parents must explicitly grant permission prior to teen outreach or teen screening, and provide the teen contact information.

No teen is ever contacted directly without prior parental permission.

No recruitment materials, screeners, or communications are sent to minors unless the parent has already granted permission for teen participation.

Recruitment described by audience segment:

Teen participants (ages 13–17)

Market research panel vendor: Teen recruitment through the vendor panel always begins with parents or legal guardians. The vendor identifies parents/guardians of teens from its existing research panel and contacts them using IRB-approved email or phone scripts. Parents/guardians receive study information and a link to the parent-facing eligibility screener. If the parent/guardian completes the screener and their teen appears eligible, the

parent/guardian is asked to grant explicit permission for the vendor to contact the teen. Only after the parent/guardian provides this permission does the vendor send the teen-specific screener directly to the teen - contact information for teens (e.g., email) will be provided by their parent/guardian. If the teen qualifies, they will provide assent and their parent will provide permission for their participation, and they will then be scheduled for a focus group.

Young Adult participants (ages 18–20)

Market research panel vendor: Young adults are recruited directly through the vendor's existing participant panel. The vendor sends IRB-approved invitations via email or phone to panelists who may qualify as young adults (i.e., ages 18–20) inviting them to complete the eligibility screener. Those who qualify and complete the informed consent process will be scheduled for a focus group.

Parents/Caregiver participants:

Market research panel vendor: Parents and caregivers are identified through the vendor's existing research panel and contacted using IRB-approved email or phone scripts. They receive study information and a link to the parent/caregiver screener survey. Those who qualify complete informed consent and are scheduled. The vendor manages all communications; Rescue does not receive contact information during recruitment or screening.

Recruitment of participants may occur up to five weeks in advance of focus groups. The procedures outlined above ensure compliance with ethical guidelines for research involving minors and satisfy IRB expectations regarding parental permission, privacy protections, and recruitment safeguards for all three audience segments.

Screening

Market research vendors and Rescue Agency recruitment staff, hereafter referred to as "recruiters", will facilitate screening recruited individuals remotely, as needed, in the following ways:

Facilitated phone screening – Recruiters will introduce themselves to adult participants and explain that we currently developing a public health campaign about youth and young adult cannabis use. As part of this campaign, we are conducting research that will inform the development of campaign messaging. This study is sponsored by the California Department of Public Health. If the contacted individuals are interested and available, the recruiter will explain that participants are selected via a screener survey that will be administered over the phone immediately following the expression of interest in the study. For participants under the age of 18, recruiters will contact parents/guardians, confirm parental interest for their teen to participate in the study, have them complete the parental screener survey questions, and if their child is eligible, obtain parental permission for their teen to participate in the screener survey. Parents/guardians will then provide contact information (e.g., email) for their teen, who will then be sent an online version of the screener survey so that they may independently complete the screener survey.

Self-administered – Recruiters will send a link to an online version of the screener survey to parents/caregivers and young adults via email or text to complete the online screener survey at their convenience. The? ?online? ?

screeener? survey will be hosted by the market research recruitment vendors using a proprietary online survey system that will? be? ?compatible? ?for? ? use? ?on smartphones,? ?tablets,? ?or? ?computers. For teen participants, the recruitment vendor may contact parents/guardians via email, confirm their interest for their child to participate in the study, and then send the teen screener survey to the teen’s email, which will be provided by the parent.

Through these modes, recruiters will sample as many individuals as possible to better ensure a diversity of ages, genders, and race/ethnicity (see Table 1, page 9). Recruiters will never turn away or decline to screen individuals who ask to fill out a screener survey. All youth and adults interested in completing a screener survey will be informed that any information they provide will be private and managed by Rescue Agency researchers, and that only de-identified data will be shared with external partners (i.e., CDPH). On the first page of the screener survey (over the phone or electronically), youth and adults will hear/read a ??brief? ?statement? ? explaining? ?the? ?purpose? ?of? ?the? ?focus groups and be asked? ?if? ? they? would be? ?willing? ?to? ?answer? ?a? ?few? ?questions? ?to?? see? ? if? ?they? ?are? ?eligible.? ?If? a potential participant agrees to participate in the screener survey, they will ?move? ?forward? ?to? complete ??the screener questions, otherwise they will not participate in screening.

The screener survey is expected to take no more than 5 minutes to complete. Youth and adults will be informed that following the completion of the screener survey, they will be contacted by a recruiter within 72 hours if they are eligible and invited to participate in a focus group.

Following recruitment activities, the recruitment vendor will review screener survey responses and identify eligible youth and adults to be invited to participate in the study. Recruitment staff will examine all responses and determine qualification based on the eligibility criteria (see eligibility in “Inclusion and Exclusion” section, page 26). Eligible youth and adults who are selected to participate in a focus group will be notified via text message, email, and/or phone call to their cell phone/landline. Consistent with institutional best practices (e.g., Medical University of South Carolina, 2018; University of North Carolina at Chapel Hill, 2024), the number of contact attempts will not exceed three for online outreach and two for phone outreach, unless the participant initiates further communication or has provided explicit consent for additional follow-up. Additionally, participants may withdraw or request no further contact at any time. Eligible youth and adults will be emailed the assent or consent form relevant for their audience segment (see Attachments: Teen Assent Form; Young Adult Consent Form; Parents/Caregivers Consent Form) and a parental permission form for those under the age of 18 for their parent to sign (see Attachments: Teen Parental Permission Form; Teen Parental Verbal Permission Script).

Attach copies of all recruitment materials.

CDPH Cannabis_Recruitment Email Templates_12.12.docx	Recruitment Materials
CDPH Cannabis_Recruitment Phone Script Templates_12.12.docx	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.

Women and minorities are included in all phases of research.

Every effort will be made to ensure that the final sample reflects the demographics of the youth and adult population in California. As such, the screener survey will collect data on age, education, race/ethnicity, gender, ZIP code, etc.

Teens (ages 13–17) are included in this research as there are significant health implications for early initiation of cannabis and its frequent use. It is important to understand perceptions about cannabis use from youth who use cannabis products or who are susceptible non-triers, because their opinions are valuable in informing campaign development. The creation of prevention strategies to help delay and/or prevent use in totality among populations under 21 (legal age for cannabis use in CA; 18 or older with a physician's recommendation) (California Department of Cannabis Control, 2025) will help prevent potentially long lasting neurological impacts and other detrimental health outcomes.

In order to identify and describe teens who use these products, we need to ask potentially sensitive questions about recent and ever use of cannabis. These questions are potentially sensitive since cannabis use among those under 21 years of age, or 18 years of age with a physician's recommendation, is illegal in California. Additionally, it is also important to understand what stressors and motivators at-risk adolescents have in their lives in order to inform tailored campaign messaging. Therefore, the study includes potentially sensitive survey- and discussion-based questions about childhood experiences. All questions are voluntary and the instructions for these questions explicitly mention that participants may skip any question they do not wish to answer. This helps to protect participants and confidentiality. Overall, by studying these audiences, we may be able to determine the types of communication that resonate best to motivate teens to avoid or quit using cannabis.

The inclusion and exclusion criteria for the three audiences are as follows:

Age: There are three audiences that represent the target age range for a potential cannabis prevention educational campaign for youth and young adults. Age will be verified at the time of screening for focus group

participation.

Inclusion Criteria:

Teen Audience: 13–17 years old

Young Adult Audience: 18–20 years old

Parents and Caregivers: 30–55 years old

Exclusion Criteria: Those not between the ages specified above will be disqualified.

Cannabis use: All audiences will be asked to self-report use of cannabis.

Teens will also be asked about susceptibility to future use (assessed by an affirmative response to susceptibility questions in the screener survey).

Teens will be segmented as either experimenters or susceptible non-triers - these segments are defined below:

Experimenter (EXP): Individuals who indicate on the screener survey that they have ever tried cannabis will be assigned to the “experimenter” category.

Susceptible Non-Trier (SNT): Individuals who respond that they have never tried cannabis, but answered with an affirmative response to any of the susceptibility questions (i.e., did not answer “definitely not” to all questions) will be assigned to the “susceptible non-trier” category.

Inclusion Criteria:

Teen Audience: Susceptible non-triers or Experimenters (1–99 times cannabis use, used within the last 12 months, but no more than 8 times per month)

Young Adult Audience: Experimenters (past cannabis use, used within the last 12 months, but no more than 15 times per month)

Parents/Caregiver: Who are not frequently talking with their child about cannabis.

Exclusion Criteria:

Teen Audience:

More than 100 times lifetime use of cannabis

Cannabis use 9 or more times per month

Those who think cannabis use poses “great risk” to their health (i.e. answered “Great risk” or “Prefer not to say” to risk of cannabis use question)

Those whose cannabis use may have been prescribed by a physician (i.e., answered “Yes,” “Don’t Know,” or “Prefer not to say” having cannabis use prescribed by a physician.)

Young Adult Audience:

Have not used cannabis in the past 12 months

Cannabis use 16 or more times per month

Those who think cannabis use poses “great risk” to their health (i.e. answered “Great risk” or “Prefer not to say” to risk of cannabis use question)

Those whose cannabis use may have been prescribed by a physician (i.e., answered “Yes,” “Don’t Know,” or “Prefer not to say” having cannabis use prescribed by a physician.)

Parents/Caregivers Audience:

Those who think cannabis use poses “great risk” to their children’s or their

own health (i.e., answered "Great risk" or "Prefer not to say" to risk of cannabis use question)

Those who report that their child's cannabis use was prescribed by a physician (i.e., answered "Yes," "Don't Know," or "Prefer not to say" having cannabis use prescribed by a physician.)

Those who report having a conversation with their children about cannabis "often"

Those who chose "Prefer not to say" when responding about their previous or current cannabis use

Adverse Childhood Experiences (ACEs): Teens and young adults will be asked to self-report on ACEs using an eight point measure. Participants will be asked "Yes, No, or Prefer not to say" in response to the following statements:

Parent or guardian divorced or separated

Parent or guardian died

Parent or guardian served time in jail

Saw or heard parents or adults slap, hit, kick, punch one another in the home

Experienced or witnessed violence in your neighborhood

Lived with anyone who was mentally ill, suicidal, or severely depressed

Lived with anyone who had a problem with alcohol or drugs

Treated or judged unfairly because of your race or ethnic group

Participants will also be asked how often (Never to Very Often, or Prefer not to say) it was very hard to get by on their family's income (e.g., to cover household expenditures like food).

How often has it been very hard to get by on your family's income -- hard to cover the basics like food or housing?

Inclusion Criteria:

Teen Audience: All Susceptible Non-Triers and 75% of Experimenters will need to report two or more ACEs;

Young Adult Audience: 75% will need to report two or more ACEs

Exclusion Criteria:

Teens: Susceptible Non-Triers who report less than two ACEs

Parents/Caregivers: Parents/Caregivers will have a specific inclusion and exclusion criteria for the focus groups to ensure their parenting experience aligns with the intended campaign audience.

Inclusion Criteria:

Focus Group: Those who self-identify as a parent/guardian of child who is 11-17 year old

Exclusion Criteria:

i. Focus Group: Those who do not self-identify as a parent/guardian of a child who is 11-17 years old

Location, Race/Ethnicity, Gender, Sexual Orientation, User Status:

Inclusion Criteria:

Focus Group: Individuals across all demographic categories (including location, race/ethnicity, gender, sexual orientation, and substance use status) are eligible to participate, provided that recruitment targets for those categories have not yet been met (see Table 1, page 9).

Exclusion Criteria:

i. Focus Group: Individuals from demographic categories for which the recruitment target has already been met at the time of screening (see Table 1, page 9).

Finally all Parent/Caregivers participants must speak English or Spanish in order to be eligible for participation.

No data will be retained for individuals who complete the screening but do not enter the study.

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.

As participants often have competing demands for their time, incentives are used to encourage participation in research. Incentives are standard practice for research and are suggested by organizations that set the standards for conducting ethical industry-led research among human subjects (CASRO, 2011). Incentives must be high enough to equalize the burden placed on participants with respect to their time and cost of participation, as well as provide enough motivation for them to participate in the study rather than another activity. Inadequate compensation for time spent participating in a study may result in a difficult and lengthy recruitment process and/or participants who agree to participate and then drop out early.

Focus group participants from the teen audience will receive a \$75 incentive to encourage attendance, cover costs associated with participation (e.g., data fees), and as a "thank you" for their time. Participants from the young adult audience will receive a \$100 incentive and parent/caregiver audience will receive a \$125 incentive to encourage attendance, cover costs associated with participation (e.g., data fees, child care), and as a "thank you" for their time. Additionally, the recruitment vendor may conduct participant referrals through their secure participant database. Consistent with respondent-driven sampling (RDS) best practices, each participant will be permitted to refer up to five peers to participate in the study. This limit aligns with CDC's National HIV Behavioral Surveillance procedures and other institutional RDS guidelines that recommend a maximum of five referral coupons per participant to minimize sampling bias and prevent undue influence (Centers for Disease Control and Prevention, 2015; Center on Human Trafficking Research & Outreach, 2025; Gile & Handcock, 2010).

Incentives will be distributed by the recruitment vendor to the participant through a gift card payment. Participants will receive their incentive at the conclusion of the focus group, or when the participant chooses to stop participation, whichever is earlier. If a participant exits or is removed from a focus group for any reason (e.g., focus group is over-booked, participant chooses to end participation early) the participant will still receive the incentive.

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.

This is a two-year study. Each participant in the teen, young adult, and parent/caregiver audience may be contacted up to three times (via virtual contact) and up to two times (via phone contact) for participation in the focus groups. During the recruitment and parental permission and/or assent/consent process, participants will have the opportunity to opt-in to be recontacted for participation in future phases of the study - i.e., Phase 2 or Phase 3. Essentially, adult participants (i.e., parents/caregivers and young adults) will be able to provide their contact information to be invited to future research activities for this study, and parents/guardians of teen participants may provide their contact information so that they can be contacted with opportunities for their teen to participate in future research activities for this study.

This section will be completely optional, and contact information will be stored separately from other survey responses. All timing allotments include 5 minutes for the screener survey, 10 minutes to complete the check-in survey and review the consent form, and 90 minutes for participating in the focus groups.

The total anticipated participant time commitment is as follows:

Teen:

105 minutes total for all Phase 1 research activities

Young Adult:

105 minutes total for all Phase 1 research activities

Parents/Caregivers:

105 minutes total for all Phase 1 research activities

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.

We have designed this research to minimize risks to participants, including asking questions that are not likely to be upsetting. The focus groups cover topics related to life experiences, values, socialization, and cannabis use behaviors - all topics which regularly are discussed in everyday life. However, some participants may feel uncomfortable or awkward discussing these topics, therefore we have taken steps to mitigate this discomfort.

(1) The content of all research will be explained to participants in the parental permission and/or assent/consent forms ensuring that all participants, including parents/guardians of teen participants are aware of the content of the research discussion. All participants, including parents/guardians of teen participants, will have the opportunity to ask the research team any questions prior to participating through access to the P.I.'s contact information, which will be provided during the recruitment and parental permission and/or assent/consent stage.

(2) Prior to participating in the focus groups, focus group moderators will verbally explain to participants that they can choose not to respond to any focus group questions at any time. Therefore, participants can simply skip focus group questions, decline to respond altogether, or stop participating without penalty. Focus group participants will be informed by email, through the parental permission and/or assent/consent forms, and by the moderator at the beginning of each group that they do not have to respond to every question, can choose to only respond to the questions they would like to respond to, and that they can stop their participation at any time.

(3) Participants can stop participation at any time without negative consequences. Even if participants have already started participating, they can leave and their survey and/or qualitative data will be deleted and destroyed. Either way, participants will still receive the incentive for their participation.

(4) All moderators will have experience leading focus groups as well as experience working with research participants. Moderators will be specifically trained on how to respond to participants in the event they become distressed.

(5) The study team requests a waiver of documentation of consent under 45 CFR 46.117(c). The only record linking participants to the study would be a signed consent or assent form; requiring a signature would therefore increase risk to participants by introducing an unnecessary identifier. Consent, assent, and parental permission will be obtained electronically, with adult participants, parents and teens indicating agreement by selecting the

appropriate options on the parental permission and/or consent/assent forms. This process ensures that informed consent is obtained while minimizing the collection of identifiable information. If this is granted, at no point would the research team have access to participants' full names. Participants will be given the option to provide their first name or a pseudonym during the focus group.

(6) No participant full names or contact information will be made available to the research team from the recruitment agency. The research team will only receive a participants' ID number and either their first name or a participant selected pseudonym. Online panel outreach protects participant's personal information, and the research team will not have access to that information at any point. However, participants will have the opportunity to provide their contact information if they wish to be contacted for future activities for this study - i.e., Phase 2 or Phase 3. This contact information will be collected during assent/consent through the parental permission and/or consent forms, and this section of the parental permission and consent forms will specify that contact information (email and/or phone number) will be used solely for research contact purposes, that providing contact information is entirely optional, that there is no penalty for choosing not to provide contact information, and that they can opt to remove their contact information from this list at any time. Participants must provide their email address and/or phone number in a specified section of the parental permission and/or consent forms, or select the statement 'I prefer not to be contacted for future projects' - any participants who select this statement will not be contacted. In the case of teen participants who are interested in recontact, we will collect their parents/guardians contact information via the parental permission forms, and no direct contact information of teen participants will be collected. Contact information provided in the Voluntary Contact Information portion of the parental permission or consent forms will be stored immediately and exclusively in a secure, password-protected file that is separate from the analytical dataset. PII will never be merged or combined with survey responses or focus group transcripts. All analytical datasets will contain only unique participant IDs with no direct identifiers. PII will be retained solely for administrative purposes (e.g., scheduling and invitation to future research opportunities) and will not be used in data analysis.

(6) The study team has established clear procedures to identify, respond to, document, and follow up on any adverse events (AEs) that may arise during participation, including events involving emotional distress, disclosure of harm or risk, or requests for assistance. These procedures apply to all participants, with additional safeguards in place for minors (ages 13–17).
Monitoring for distress during focus groups: All focus groups will be facilitated by trained moderators who receive specialized instruction in recognizing verbal and nonverbal indicators of participant distress (e.g., crying, heightened anxiety, withdrawal from the conversation, disclosures of harm to self or others). A research support staff member will attend all sessions to assist with monitoring and responding to potential AEs. Moderators will routinely remind participants that they may skip any question or stop participating at any time without penalty.
Intervention procedures: If a participant exhibits signs of discomfort,

distress, or emotional harm, the moderator will immediately initiate a private Zoom chat to check in with the participant and offer support. Participants may take a break from the group, turn off their video, or withdraw entirely if they choose. When appropriate, the moderator or research support staff will provide the participant with age-appropriate resource lists, including crisis hotlines, community mental health services, teen-specific support services, and other relevant referrals. These resources will be delivered privately (e.g., via private Zoom message) to protect confidentiality.

Additional procedures for teen participants: For teen participants, additional protections will be implemented whenever a moderator identifies distress or a teen discloses a safety concern. If a teen indicates immediate risk of harm to self or others, the moderator or support staff will:

Provide crisis resources via private message;

Assess whether emergency services need to be contacted; and

Notify the teen's parent/guardian that their child expressed distress or may require additional support, consistent with parental permission requirements and mandated reporting obligations.

Parents/guardians will be contacted only when the situation involves a safety risk, the teen requests help involving their parent, or reporting is required by law.

We minimize the collection of personally identifiable information (outside of voluntary contact information used solely for communications about future study opportunities); participants are not required to provide their names on consent, assent, or parental permission forms. Instead, informed consent, teen assent, and parental permission are documented electronically through a required checkbox indicating voluntary agreement to participate in the research. Digital records of these consent, assent, and parental permission confirmations are stored in secure, access-restricted files at Rescue Agency. As with any research study, there remains a minimal risk that confidentiality could be compromised; however, we have taken steps to substantially mitigate this risk by minimizing the collection of identifying information, limiting the length of time that any contact information is retained, and implementing strong digital security protections. These measures collectively reduce the likelihood of a confidentiality breach while ensuring that informed consent, assent, and parental permission are appropriately documented.

Unique participant IDs will be used in lieu of identifying information whenever possible for focus group participants. Participants will be assigned a unique ID by the market research recruitment vendor to use in all check-in surveys, focus group discussions, and statement surveys.

For focus groups, it will be necessary for researchers to have access to a grid that includes the participant's first name or a provided pseudonym and the unique ID code. However, we have minimized the length of time that this information is retained. Approximately twenty-four hours prior to the beginning of each focus group a participant check-in grid will be filled out by the recruitment vendor that includes the participant's first name and unique ID code through a shared secure drive. This will allow Rescue Agency researchers to confirm that all electronically completed parental permission and/or assent/consent forms have been received for the focus group and to

confirm which participants show up for the focus groups. At the conclusion of the focus group Rescue Agency researchers will record the unique IDs for participants who participated and then destroy the grid.

Within 1 hour of the conclusion of each focus group, audio recordings will be uploaded to a secure, encrypted private drive that is only accessed by the Rescue Agency research team.

For focus groups, all audio files will be transcribed. All transcribers will sign a confidentiality agreement (see Attachment: Confidentiality Agreements). After transcription, all audio files will be erased (no later than 1 year after the focus group). Participants will be advised not to share any personally identifying information, like their last name during discussions, regardless, the transcriptions will be reviewed by a member of the research team and any identifiable information will be removed. The de-identified transcripts will then be used for subsequent qualitative data analysis. Additionally, de-identified data (e.g., contact details, addresses, and other unique identifiers will be removed so that no one can reasonably trace the data back to a specific person) will be shared with the California Department of Public Health (CDPH) who may retain the data beyond three years.

External partners from California Department of Public Health (CDPH) will not interact directly with participants, will only observe focus groups through the live stream, and will not have access to any linked data or be involved in data management, processing, analysis, or reporting. All data shared with CDPH will be cleaned and de-identified by Rescue Agency.

All data is securely transmitted and stored as described in the discussion of digital security in the sections below.

All study activities, including surveys and focus groups will be conducted virtually. For virtual focus groups, Zoom collects information that a participant gives them to access the platform (e.g., name, email address and/or phone number). Zoom also collects additional data once the platform is accessed such as IP address, MAC address, device type, etc. Researchers will not have access to any data that participants provide to use Zoom or any data that Zoom collects while the platform is in use. Furthermore, researchers will not have the ability to link data obtained from Zoom to any participant. The full privacy policy for Zoom can be found at: <https://zoom.us/privacy>. Zoom includes a number of security protection features including, but not limited to, the ability to lock a meeting so no one else can join, restrict screen-sharing to the host only, enable a waiting room to restrict access to only participants who are invited to join, and remove a participant, if needed.

Contact information (email or phone number) may be voluntarily provided for scheduling and/or future research contact. All identifying information is stored in a secure file separate from all response data and cannot be linked back to participant responses. Research data used for analysis contain only unique participant IDs with no direct identifiers.

AUDIO/VIDEO RECORDING RISKS

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

While all participants will be audio recorded, it is not expected that audio-recording will increase risk to participant confidentiality. Within 1 hour after each focus group, recordings will be uploaded to a private drive that is only accessed by the Rescue Agency research team.

Given that this study will be conducted virtually, all audiences (teens, young adults, and parents/caregivers) will be required to share their audio and encouraged to share their video while using Zoom for focus group participation. All participants will be required to share their audio and encouraged to share their video during the focus groups, however video sharing is not mandatory and participants can choose to remain off camera.

Therefore, confidentiality could be compromised in the following ways:
Example: If someone sees a participant's computer, tablet, or mobile device screen or hears the participant responding to questions, they may know that a participant is talking about issues related to cannabis. To mitigate this concern, participants will be reminded that it is very important that they use a computer, tablet, or mobile device in a private place and/or wear earphones or headphones during participation.

Example: There is the possibility that other participants can obtain and use another participants' likeness by the use of recording (e.g., video or audio of a computer, tablet, or mobile device output). To mitigate this concern, researchers will ensure that the participant facing record functionality in Zoom is disabled, but participants could still use third party recording software to obtain video or audio of a participant's voice.

Although focus groups will not be video recorded, focus groups will be live streamed. However, it is not expected that live-streaming will increase risk to participants' confidentiality. This is done to allow Rescue Agency non-research staff and external partners (i.e., CDPH) to observe the focus groups. Access to live streaming will be granted by invitation only through a unique link that will only be shared with external partners from California Department of Public Health and Rescue Agency, who will watch the group in a private room. Live streaming and audio recording for this study is mandatory, therefore all participants must agree to the live stream and audio recording in the parental permission and/or participant consent/assent forms.

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.

The risks of participation are similar to those experienced in everyday life. Therefore, it is not expected that participants will experience any mental or physical effects directly related to research activities. If medical services are necessary, research staff will call 9-1-1 or proper medical authorities. No additional services will be provided. The Principal Investigator (PI) will ensure that there are appropriate oversight systems in place to monitor all research activities and identify any adverse events. Furthermore, the California Department of Public Health will be actively involved in monitoring the study by conducting regular oversight calls with the PI. However, if the occurrence of an adverse health event or unanticipated problem were to occur and increase the risk of harm for participants, the PI will ensure that this matter is reported to the IRB and that appropriate measures to modify the protocol are implemented immediately.

Oversight Systems of General Research Activities

Staff Training and Certification:

Mandatory Training: All Rescue Agency researchers will complete PHRP Human Subjects Research training and receive specialized training on this protocol, including the consent process, eligibility screening, data security procedures, and the specific focus group guide/survey instrument.

Fidelity Checks: Focus group facilitators will be trained to adhere strictly to the approved script. The PI or co-investigator will review the first 2–3 focus group transcripts to ensure fidelity to the discussion guide and proper implementation of distress management protocols.

Data Quality and Protocol Adherence Monitoring:

Survey Data Review: The PI will review the survey data completion rates and logic checks (e.g., review of open-ended responses for signs of distress) on a weekly basis.

Regular Team Meetings: Weekly project meetings will be held with all research staff and external partners to discuss recruitment status, review any deviations from the protocol, address logistical challenges, and reinforce security and confidentiality procedures.

Monitoring and Management of Adverse Events (AEs):

Given the study populations and the sensitive nature of the topic (cannabis use), a robust system is established for the detection and management of AEs:

Identification of Participant Distress (Focus Groups):

Trained Facilitators: Focus group facilitators will receive training on recognizing signs of distress or emotional discomfort, which may include crying, overt anxiety, or disclosures of immediate risk (e.g., self-harm, harm to others).

Immediate Intervention Protocol: If a participant appears distressed, the facilitator will:

Immediately offer a private chat/break to the participant within the virtual platform. If the participant accepts, they will be given a chance to step away

from the group. If the participant discloses immediate risk, the facilitator will utilize a referral resource list to provide immediate, accessible support services (e.g., national crisis hotlines, local mental health resources). The participant will be reminded of their right to withdraw from the focus group at any time without penalty.

AE Documentation and Reporting:

AE Log: All instances of participant distress or disclosures requiring intervention will be immediately documented by the PI in a secure, confidential AE Log, regardless of whether they meet the definition of a Serious Adverse Event (SAE). This log will include the date, a description of the event, and the action taken.

IRB Reporting:

Serious Adverse Events (SAEs): Any event meeting the definition of an SAE (e.g., unexpected, related to the research, and resulting in injury or death, or placing the participant at greater risk) will be reported to the IRB within 24 hours of the PI becoming aware of the event.

Non-Serious AEs: All other documented AEs will be summarized and submitted to the IRB as part of the regularly scheduled Continuing Review.

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.

It would be possible to completely refrain from audio recording the focus groups, which would require the research team to rely on note-taking of conversations rather than transcripts. However, audio-recording and subsequent transcripts dramatically increase the accuracy of theme identification in data analysis. Relying exclusively on note-taking of conversations may result in missing key themes and information that could be important in informing the development of educational messages for this audience. Therefore, although avoiding audio recording conversations may be less risky, it would result in less complete data, a poorer understanding of cannabis knowledge and use among youth in California, and less accurate data about the deterrents and motivators of cannabis use.

It is also possible to completely refrain from video sharing and rely on audio only. However, video viewing assists with rapport building, comfortability, and relatability of the moderator and participants. Therefore, although avoiding video may be less risky, it would result in less rich data and limit the study experience for the participant. Still, all participants will have the option to choose whether to share, or not share, their video during the focus group and will have the option to exit the study at any time, without penalty, if they no longer wish to be audio recorded.

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 findings from these focus groups and accompanying check-in surveys are expected to help the California Department of Public Health conceptualize, develop, implement, and market test an age-specific, developmentally appropriate, and scientifically accurate media and social marketing campaign to educate youth and young adults on the risks and consequences of cannabis use. If future messaging were to reach these participants and their peers, the educational messages could foreseeably help reduce the early initiation of cannabis use among youth. Participation in focus groups on this topic may also increase awareness and understanding of youth cannabis-related risks, delay or prevent initiation, reduce frequency of use among youth, and enhance knowledge of health effects and responsible cannabis use across all three audiences.

JUSTIFICATION OF RISKS

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

The potential risks to participants in this study are minimal. As with any research study, there is a chance that confidentiality could be compromised, but efforts are taken to reduce the chance of this risk (described previously, pages 30–34). Additionally, participants may experience discomfort related to discussions, but they can choose not to answer questions or withdraw from the study at any time. While the research may immediately benefit the participants if they are made aware of the risks of cannabis use, in the long term, this research will contribute to the improvement of cannabis education, prevention, and awareness, which could help these participants and their peers prevent potential cannabis-related negative health outcomes in the future. Based on this study being of minimal risk to participants, the potential benefits to their communities outweigh the risks.

Administrative 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)

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 Rescue Agency research members who are directly involved in the research and who will have direct contact with participants, such as moderating or assisting, will have gone through either NIH Office of Extramural Research Protecting Human Subjects or Protecting Human Research Participants (PHRP) training. This is to ensure that participants are treated fairly and ethically, and that human subjects are protected at all stages of the research process. The aforementioned training covers regulations and best practices addressing specific data security policies, standards and procedures in regard to personal disclosure in spoken or written form, physical security of hard copy materials during collection, transmittal, processing, and storage, and electronic security in terms of data files, emails, Internet transfers, and removable media (e.g., CD-ROM). All Rescue Agency research and non-research staff will also sign a confidentiality agreement prior to conducting focus groups (see Attachment: Confidentiality Agreements).

STAFF VETTING PROCEDURES

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

All staff with access to PID will have undergone federal background checks as part of the hiring process for Rescue Agency and will have signed a confidentiality pledge stating that no sensitive data will be released to unauthorized personnel. Additionally, all staff with access to PID are required to undergo regular trainings covering topics such as regulations and best practices addressing specific data security policies, standards and procedures in regard to personal disclosure in spoken or written form, physical security of hard copy materials during collection, transmittal, processing, and storage, and electronic security in terms of data files, emails, Internet transfers, and removable media (e.g., CD-ROM). In addition to these trainings, all staff with access to PID will review the complete IRB package and must verbally explain the correct procedures with regards to PID prior to being given access to this information to the project PI.

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.

CDPH Letter of Support.pdf Department Letter of Support

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.

The data from this project will be hosted using industry standard firewalls and rigorous security practices. The only people with access to PID collected during this study are trained Rescue Agency research team members. The final data files will be de-identified, and then will reside on Rescue Agency password protected file storage folders for the project. The folder is only accessible to the study research team. De-identified data files will be provided directly to the study sponsor, the California Department of Public Health, who will maintain the data file as a password protected file on their secure server.

Computer access for research staff to the PID at Rescue Agency are protected through the use of username and passwords. Operating systems are kept current to the latest stable releases and updated with applicable security patches as they are made available by the vendors. Rescue Agency subscribes to various security alert services to stay informed about current security issues or product vulnerabilities. A hierarchical storage management and integrated backup and recovery system is used to efficiently protect data. To prevent data loss, daily system backups are made across all network directories. Procedures are in place to respond to early warnings about security threats whether during or outside regular business hours. Our response protocol includes immediate action to protect systems, inform users, and gather information and apply new protective measures such as newly released security software updates. All Rescue Agency employees will sign a confidentiality pledge stating that no sensitive data will be released to unauthorized personnel.

Aggregate and de-identified data from this study may be used in future research and/or shared with external partners, but again, no identifiable information will be retained after the conclusion of the study or included in these results. Participants will not be contacted again for this study for any reason, with the exception of those who opt to complete the Voluntary Contact Information portion of the parental permission or consent forms and who may be contacted to participate in future activities of this study if they are interested at that time.

De-identified data (e.g., transcripts, demographic information from screeners, short audio clips from discussions) from this study will be kept by Rescue Agency for three years after the study ends. It will be stored on a password-protected computer or in a locked cabinet. Three years after the study ends, Rescue Agency will destroy all of the data by securely shredding and permanently deleting records. Additionally, de-identified data (e.g., contact details, addresses, and other unique identifiers will be removed so that no one can reasonably trace the data back to a specific person) will be

shared with the California Department of Public Health (CDPH) who may retain the data beyond three years. External partners from California Department of Public Health (CDPH) will not interact directly with participants and will only observe focus groups through the live stream, and will not have access to any linked data or be involved in data management, processing, analysis, or reporting. All data shared with CDPH will be cleaned and de-identified by Rescue Agency.

CONFIDENTIALITY OF PUBLISHED DATA

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

Identifying information will not be published that could possibly be used to identify an individual subject. Aggregate data from this study may be used in future research and/or shared with external partners (i.e. CDPH), but no identifiable information will be retained after the conclusion of the study or included in these results. All data will be completely de-identified after data collection is complete and prior to analysis, and it will not be possible to link individuals to their responses. In order to protect the identity of individual subjects, when conducting analysis on subsamples (e.g., susceptible non-triers or experimenter teens), we will ensure that the smaller group size does not lead to unintended disclosures.

To mitigate this risk, we will implement the following confidentiality protections:

Separate reporting of demographics and insights: Demographic information (e.g., age distribution, race/ethnicity, gender, region) will be presented only in aggregate form on a standalone slide, independent from any quotes or thematic insights.

Anonymized qualitative reporting: Participant quotes will not be attributed to an individual with specific demographics (e.g., "17-year-old Latina from Fresno"), but instead to high-level descriptors (e.g., "Teen participant").

No disaggregation for small subsamples: When analyzing or presenting findings from smaller subgroups (such as "susceptible non-triers" or "experimenter teens"), results will only be reported at the thematic level, and only when data are sufficiently aggregated to prevent identification.

Together, these procedures help us ensure that findings from all participants, including those in small samples, are shared in a manner that maintains confidentiality and eliminates risks or unintended disclosure.

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?

This project is expected to take approximately 24 months to complete. This is expected to be a reasonable amount of time for the formative research (Phase 1), for the brand and message testing concepts to be developed, for those concepts to be tested through brand and creative message testing (Phase 2), and for the educational messages to be refined and launched throughout the state (Phase 3). The quantity of data requested is based on the objectives of the research study. Given that there is very limited data available about youth cannabis use we are requesting formative qualitative research with approximately N=156 (Phase 1) individuals in order to gain a greater understanding of youth cannabis use among Californians, and their perspectives on drivers for early initiation and frequent use of cannabis. Once messages are developed, qualitative research will be conducted with approximately N=126 (Phase 2) individuals, to confirm the educational messages are effective. Finally, the final campaign materials will be tested with approximately N=54 (Phase 3) individuals to ensure the campaign materials are functioning as intended with no unintended consequences. These requested total number of participants (N=336 across Phase 1, Phase 2, and Phase 3) are the minimum number of individuals required to adequately carry out these efforts.

In this current IRB protocol, we are only requesting approval for Phase 1: Formative Research.

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 will be limited only to those who are qualified and with a need to know for purposes of implementing or evaluating the research. This will include the research team who is implementing research at Rescue Agency and de-identified data will also be shared with external partners at California Department of Public Health who are sponsoring the research. All data will be de-identified prior to analysis.

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.

The identity of individual subjects will be protected across all three audiences. Following the methods described above, all data will be de-identified prior to analysis. In order to protect the identity of individual subjects, when conducting analysis on subsamples, we will ensure that the smaller group size does not lead to unintended disclosures. For example, when data is collected from locations with a small total population, the specific location, size of the town or other community characteristics that may lead to identification of the location will not be reported. Finally, across data collection, the confluence of identifiers such as characteristics of family structure, details of personal characteristics, or other expressions of individuality will not be reported together in order to avoid incidental identification of subjects. Any published documents will not include information that could possibly be used to identify an individual participant.

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

CDPH Cannabis_Data-Security-Letter_Rescue-Agency.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 de-identified?

data will be de-identified

Explain what identifiers will be removed and how.

Once research is concluded, all PID will be destroyed. We will provide CPHS with a letter certifying that this has occurred.

All personally identifiable information (PID) will be removed from the data prior to analysis and any sharing. This includes participant names, contact information (e.g., phone numbers, email addresses, home addresses), Zoom display names, and any other unique personal characteristics or details that could reasonably lead to re-identification. Audio recordings will be transcribed and then deleted within one year of the focus group. During transcript review, research staff will redact any spoken identifiers or incidental details that could identify a participant. To further protect confidentiality, small cell sizes and location-specific characteristics will be generalized so individuals cannot be inferred based on subgroup attributes. After de-identification, data will be stored on secure, password-protected systems accessible only to authorized study personnel, and only the fully de-identified dataset will be shared with the study sponsor.

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.

Data will not be collected in paper form.

FAXING

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

Data will not be faxed or sent through fax machines.

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.

Information with any PID will not be mailed.

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 in paper or electronic form will never be left unattended in cars or at any other unsecured locations. Data will never be stored in USB drives or CDs and only in our secure electronic file system.

All entryways to Rescue Agency facilities are locked at all times. Staff have key fobs that permit entry to Rescue Agency facilities. Guests must ring a doorbell for entrance to the reception area where they are escorted. All visitors are required to follow the same confidentiality procedures if they should come into contact with materials or discussions having confidentiality implications. All data stored will not be accessible to anyone outside the research team.

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.

Rescue Agency has well defined access control procedures and monitored alarm services. The procedures limit who can access the facilities, who has electronic access to PID, along with the police force and dispatch that monitor and respond to alarms 24x7.

SERVER SECURITY

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

All electronic files are encrypted. All PID in this study is electronic, and is encrypted.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

All PID will be destroyed after data collection or stored separately from analysis data (consent form; voluntary contact information from the parental permission and consent forms for participants who agree to be recontacted for future phases of this study). Any PID recorded during recruitment for individuals who are not interested in participating will immediately be deleted if they decline interest. Any data used for data analysis will be de-identified with any PID prior to data analysis.

DISK STORAGE

State whether all disks with PID will be destroyed.

No data will be stored on disks at any point during the research process.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All computer access will be protected through the use of encryption, passwords and other protections. All data will reside on Rescue Agency password protected file storage folders for the project, backed up through our secure cloud storage and that is only accessible to the Rescue Agency research team. Screener survey data and data from the focus groups, including audio files and check-in survey responses, will be directly uploaded to our secure, password protected cloud storage, only accessible by the Rescue Agency research team. Computer access for moderators and research staff to secure servers at Rescue Agency is protected through the use of username and passwords. The servers are protected behind sophisticated firewalls with an extensive array of virus protection and only selected project staff (i.e., Rescue Agency researchers) are allowed access to project drives and servers that contain participant contact information and data. In the case where data must be transported between the recruitment vendor and Rescue Agency's password protected file storage system, all data will be both encrypted and password protected, and uploaded directly to Rescue Agency's secure storage system.

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 Rescue Agency workstations are FIPS 1402 compliant, encrypted using XTS-AES-128 encryption with a 256-bit key via FileVault. Programs and sensitive data are stored in locations on network servers accessible only by restricted passwords and special access mechanisms.

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 Rescue Agency laptops are FIPS 1402 compliant, encrypted using XTS-AES-128 encryption with a 256-bit key via FileVault.

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.

No data will be kept on any 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.

All workstations, laptops and servers that store data use Google Workspace which is equipped with secure RSA 2048 bit encryption, HTTPS sessions, 2-step verification, suspicious login monitoring, S/MIME email security, data loss prevention, spam/malware detection, and phishing prevention. All work accounts must be authenticated with username/password credentials and workstations, laptops, and servers have security patches tested and installed within 72 hours while major security patches are implemented in 24 hours.

PASSWORD CONTROLS

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

All workstations, laptops and servers accessing PID obtained in support of this research will retain a password with a sufficient level of complexity, including a minimum of nine characters with at least three of lowercase letters, uppercase letters, numerals or punctuation. To ensure protection, passwords will be changed every 6 months.

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.

In addition to requiring automatic screen timeout for all workstations and laptops, Rescue Agency also engages in periodic security log reviews, anti-virus/malware/spyware protection, audit trails on all relevant devices, and intrusion detection.

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.

In the case that it was necessary to transmit electronic PID outside the secure internal network, the files would be encrypted using software which is compliant with FIPS 140-2.

INTERNET ACCESSIBILITY

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

While participant names are submitted in the online parental permission and assent/consent forms that are collected online, this information is not accessible to the broader Internet. The online platform uses Transport Layer Security encryption for all transmitted data, is independently audited using the industry standard SSAE-16 method, and deploys the general requirements set forth by many Federal Acts, including the FISMA Act of 2002. The online platform meets or exceeds the minimum requirements as outlined in FIPS Publication 200. As such, names on electronic consent forms are not accessible to the Internet.

DISPOSING OF PID

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

Multi-pass secured wiping and physical destruction will be employed in the case of disposing of electronic PID.

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.

For Adults (over the age of 18)

We are requesting a waiver of informed consent for the screener survey questions that determine participant eligibility for the focus groups. Prior to completing the screening questions, participants will be verbally briefed or will read a brief statement (for online screener surveys) explaining the purpose of the study, asking if they would be willing to answer a few questions to see if they are eligible for the study including personal questions about demographics and past and current cannabis use. They will be informed that participation is voluntary and that they can stop participation at any time (see Attachments: Young Adult Screener Survey; Parent/Caregiver Screener Survey). Individuals will then be asked if they would like to move forward with the screener questions. If they verbally agree, individuals then complete the screener survey.

Once participants have completed the screener survey and qualified for participation they will complete a formal consent process. In the case of panel recruitment conducted over the phone, participants will be sent the consent form via email and will be asked to download and review it. For individuals who qualify, consent documents are not read aloud in full during a phone conversation due to their length; instead, participants review the written forms while staff are available by phone or email to answer questions.

At the conclusion of the review of the consent form via phone call, the participant indicates if they would like to participate. The participant is asked to download a copy of the consent form and the participant bill of rights by the recruitment vendor. Participants are asked to check a box on the consent form and upload it directly to the panel recruitment agency's secure server. The informed consent sheet includes a description of the project focus group. It also covers estimated time commitment, benefits and risks, confidentiality and privacy, voluntary participation, and information about where to direct questions (see Attachments: Young Adult Consent Form; Parent/Caregiver Consent Form).

For Youth (under the age of 18)

The procedures for youth are similar to the above, with these additional caveats.

All outreach and recruitment of teen participants will begin with their parents/guardians. Parents/guardians will receive information about the scope and purpose of the study, and asked to answer a few screener questions to determine if their teen may be eligible for participation. If the teen may be eligible, and the parent/guardian provides permission and their

teen's contact information (e.g., email), the recruitment vendor will send the teen screener survey to the teen participant. For teens, all completed parental permission and assent forms must be returned to the recruitment vendor before they are scheduled to participate in a focus group (i.e., parent/guardian permission form, and a participant assent form) (see Attachments: Teen Assent Form; Teen Parental Permission Form).

Parents/guardians will be asked to review and check a box on the parental permission form which provides clear and simple instructions for how a parent/guardian can provide or reject consent in writing. Recruiters will inform parents/guardians that the parental permission form must be completed and returned at least 24 hours prior to their teen starting any research related activities outside of screening. In instances where a parent/guardian may have completed the parental permission form prior to screening, their permission will extend to the focus group participation. All parental permission forms and assent forms must be completed and returned via direct upload to the recruitment agency's secure server, before teens are scheduled for a focus group. If a parent/guardian chooses not to give consent for their child to participate, the recruiter will document this decision and the youth will not be eligible for participation.

Informed Assent/Consent Process

The screener is administered first, followed by notification of eligibility, and then the distribution and completion of the parental permission and/or consent/assent forms. Minors are only contacted after parental permission is obtained, and the Rescue Agency research team does not access participant contact information at any stage of recruitment.

Administration of eligibility screener:

Market research panel vendor: Individuals are contacted by the vendor using their preferred contact method (email or phone) previously provided to the vendor.

Online Screener (most common): Participants receive an IRB-approved email invitation with a link to the secure online screener. Parents of teens complete the parent-facing screener; only after parental permission is given will teens receive a link to the teen screener.

Phone Screener (when preferred or needed): The vendor may administer the screener orally over the phone using the same scripted questions contained in the online version. For teens, the phone screener is administered only to the parent; the teen completes their own online screener only after the parent grants permission.

Notification of eligibility:

Throughout recruitment, eligibility determination is within 72 hours:

Once the screener is submitted, the vendor's system evaluates eligibility.

If eligible, the vendor informs the individual directly (via email or phone, depending on the contact method) that they qualify for a focus group.

The vendor confirms the participant's continued interest and schedules them for a group based on their availability.

For minors, the parent is notified of eligibility, and the teen is only contacted after the parent gives explicit permission.

Consent and Assent procedures:

Timing and distribution:

After eligibility is confirmed:

Participants are emailed the appropriate consent form, parental permission form, assent form, and the California Experimental Subject's Bill of Rights. These documents are provided electronically, allowing participants to read them at their own pace and ask questions before signing.

Consent documents are not read aloud in full during a phone conversation due to their length; instead, participants review the written forms while staff are available by phone or email to answer questions.

Mode of consent:

Adults (parents/caregivers and young adults 18–20): Provide electronic consent by checking a box on the consent form and uploading to the secure server

Parents of teens (13–17): Provide parental permission by checking a box on the consent form and uploading to the secure server.

Teens: Complete the assent form by checking a box on the consent form and uploading to the secure server. Both parental permission and teen assent must be on file before scheduling.

Confirmation and scheduling:

Only after the completed parental permission and/or consent/assent forms are received does the vendor finalize the participant's placement in a scheduled focus group. No individual may participate without completed documentation.

These procedures ensure comprehension, protect minors, and meet IRB requirements across all recruitment modalities.

The completed parental permission and/or assent/consent forms for all audiences are transferred from the recruitment agency's secure server to Rescue Agency's secure electronic file system where the Rescue Agency research staff can review prior to the beginning of any focus group. No focus groups will be conducted without Rescue Agency research staff confirming receipt of parental permission and/or assent/consent forms, with permission and or assent/consent boxes checked, and confirming during the focus group whether the participant has consented to audio recording and live-streaming.

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.

[04_29] CDPH Cannabis_YA Consent Form.docx	Consent Form
CDPH Cannabis_Parents_Caregivers Consent Form_8th Grade Reading Level[12:12].docx	Consent Form
CDPH Cannabis_YA Consent Form_8th Grade Reading Level_[12:12].docx	Consent Form

TRANSLATED DOCUMENTS

Provide copies of the non-English version of consent/assent forms and/or scripts to be used in this research.

CDPH _Parents_Caregivers Consent Form_Spanish[12:12].docx	Consent Form
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TRANSLATOR

Provide a copy of the curriculum vitae of the translators(s) and/or proof of certification of the translation firm.

CPHS may reject poorly written documents or documents from translators lacking adequate proof of training or expertise. For studies using documents translated into Spanish, the translation should use formal language.

CDPH Cannabis_Declaration of Certified Translation.pdf	Translator Curriculum Vitae
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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.

For Youth (under the age of 18)

The procedures for youth are similar to the above, with these additional caveats.

All outreach and recruitment of teen participants will begin with their parents/guardians. Parents/guardians will receive information about the scope and purpose of the study, and asked to answer a few screener questions to determine if their teen may be eligible for participation. If the teen may be eligible, and the parent/guardian provides permission and their teen's contact information (e.g., email), the recruitment vendor will send the teen screener survey to the teen participant. For teens, all completed parental permission and assent forms must be returned to the recruitment vendor before they are scheduled to participate in a focus group (i.e., parent/guardian permission form, and a participant assent form) (see Attachments: Teen Assent Form; Teen Parental Permission Form).

Parents/guardians will be asked to review and check a box on the parental permission form which provides clear and simple instructions for how a parent/guardian can provide or reject consent in writing. Recruiters will inform parents/guardians that the parental permission form must be completed and returned at least 24 hours prior to their teen starting any research related activities outside of screening. In instances where a parent/guardian may have completed the parental permission form prior to screening, their permission will extend to the focus group participation. All parental permission forms and assent forms must be completed and returned via direct upload to the recruitment agency's secure server, before teens are scheduled for a focus group. If a parent/guardian chooses not to give consent for their child to participate, the recruiter will document this decision and the youth will not be eligible for participation.

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.

[04_29] CDPH Cannabis_Teen Parental Permission Form.docx	Assent Forms
[04_29] CDPH Cannabis_Teen Parental Permission Verbal Script.docx	Assent Forms
[04_29] CDPH Cannabis_Teen SNT & EXP Assent Form.docx	Assent Forms
CDPH Cannabis_Teen Parental Permission Form_8th Grade Reading Level_[12:12].docx	Assent Forms
CDPH Cannabis_Teen Parental Permission Verbal Script_[12:12].docx	Assent Forms
CDPH Cannabis_Teen SNT & EXP Assent Form.docx [6th Grade Readability)_[12:12].docx	Assent Forms

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

Amendment Changes

List the pages and questions that have been changed.

Changes for this protocol amendment were made on Page 5 (Compensation). These updates can also be found in the newly attached protocol documents on pages 4 and 11.

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

2025 CDPH IRB Budget.docx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

2025 CDPH IRB Protocol Cover Letter.pdf Cover Letter

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.

Notify IRB for Pre-Screening

- Submitted 05/20/2026 8:41 PM ET by Sussan Atifeh

Internal IRB Screening

The questions on this page will be blank when an amended copy is submitted. If the form is returned during the amendment review, the questions on this page will appear as answered previously during the amendment review (responses from the initial review will not appear)

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

The Chairs requested that this amendment to be discussed in the June 5th 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

June

Assign to cycle year

2026

Chair Review and Full Board Set-Up
- Submitted 05/21/2026 2:36 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2025-178

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 Chairs requested this amendment to be discussed in the June 5th full board meeting.

Assign SME to study

David Lang

Enter the meeting date for this project

06/05/2026

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.

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