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

View xForm - Project Application v6

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

Data entry
- Submitted 11/11/2025 3:13 PM ET by Danny Azucar, PhD, MPH

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

December 2025 cycle.

_____New HSC Project_____

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11/06/2025 • Sussan Atifeh • Internal

Researchers from the Rescue Agency, in partnership with the California Department of Public Health – Substance and Addiction Prevention Branch (CDPH-SAPB), have submitted this application to request approval for a project with human subjects' contacts components.
The project is aimed to better understand perceptions, beliefs, and social norms surrounding cannabis among California teens, young adults, and parents/caregivers. Findings will directly inform statewide prevention messaging to support healthy, informed decision-making among youth.

• Data-Source Department(s):
Per researchers there is no request for state data in this study —A LOS from the California Department of Public Health, Substance and Addiction Prevention Branch (CDPH-SAPB) is attached.
----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.

• Project's site:
Rescue Agency—A DSL from Rescue Agency is attached

• LINKAGES:
No

• Funding:
Yes—State funded by California Department of Public Health, Substance and Addiction Prevention Branch

• Non-English translations:
Yes— Teen and young-adult sessions will be in English; parent/caregiver sessions will be in English and Spanish.

• End Product:
The project will result in a scientifically grounded, statewide prevention campaign, with findings summarized in reports and related publications.

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11/06/2025 • Sussan Atifeh • Internal

Dear Researchers: Thanks for addressing the majority of the comments. Please check all pages of the application (scroll down to see the entire page) and address the new or previous minor comment(s) that are NOT tagged as "Resolved" and resubmit the application. Thanks,

11/10/2025 • Sussan Atifeh • *Not* Internal • Resolved

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

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Danny Azucar, PhD, MPH

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

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

Rescue Agency

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

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

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

California

Attach a copy of the PI's Curriculum Vitae.

Danny Azucar Curriculum Vitae PI Curriculum Vitae

Deleted Attachments: 1 (Most Recent: Danny Azucar, PhD, MPH - CV on 11/05/2025 8:19 PM ET)

CO-PRINCIPAL INVESTIGATOR (CO-PI)

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

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

No answer provided.

ADMINISTRATIVE CONTACT

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

Danny Azucar, PhD, MPH

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

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

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

Dawnyéa Jackson, PhD

Email: djackson@rescueagency.com **Business:** 202-871-6550 EXT:251

OTHER RESEARCH STAFF

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

Please ensure you have listed in this section "all" research staff who interact directly with participants (as in interviews or focus groups) or who will have access to the data.
• This includes individuals who will have access to the linked de-identified data if that data file will contain any data fields that were originally in the state data.
• This includes all research staff who are involved with data management, data processing or analysis and write-up, etc.

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Are there any CDPH research staff involved in this study who will either:

• Interact directly with participants (e.g., through interviews or focus groups), or
• Have access to study data?

This includes:

• Anyone who will access linked, de-identified data if that file contains any fields originally from state data.
•Staff involved in data management, processing, analysis, or reporting.

---If yes, please list those individuals in this section.

---If no, please include a statement in the “Study Procedures” section confirming that no CDPH research staff will be involved in participant interaction or have access to study data.

thanks.

11/10/2025 • Sussan Atifeh • *Not* Internal • Resolved

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

Molly Barry, MS
Email: mbarry@rescueagency.com **Business:** (858) 342-1465
Samantha Jacobs, MPH
Email: sjacobs@rescueagency.com **Business:** 619-213-7555 ext. 153
Shiloh Beckerley, PhD
Email: sbeckerley@rescueagency.com **Mobile:** (858) 366-8189
Allison Parsons, PhD
Email: aparsons@rescueagency.com **Business:** (803) 553-1240
Priscilla Fernandez, PhD
Email: pfernandez@rescueagency.com **Business:** 619-231-7555 ext 167
Josh Causey, BSc
Email: jcausey@rescueagency.com **Business:** (619) 231-7555

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

False

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

PROJECT SITE

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

If the main site of this project is 'Rescue Agency', please select it from the dropdown menu. thanks.

• Note: The main site(s) refer to the institution(s) responsible for the primary storage, receipt, and management of study data, as well as for ensuring data security and compliance with relevant regulations. This includes overseeing access controls, data encryption, and privacy safeguards. Typically, this is the Principal Investigator’s institution, which houses and manages the servers through which the data is processed.

11/06/2025 • Sussan Atifeh • *Not* Internal • Resolved

Rescue Agency

STUDY PROCEDURES

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

Have you requested any state data (for contacting subjects) to conduct this study? If yes, please select "Data Registry" in this section as well. If no, you can disregard this comment.

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If you have requested state data from any state departments, please select "Data Registry" in this section and please attach all lists of requested variables (using descriptive names) by attaching the formal data dictionaries in the "DATABASE DETAILS" section.
In the attached list(s) you need to provide a brief explanation to justify requesting each variable and to show the use of the variables. Thanks.

• If you do not have access to the formal data dictionaries, you can create a Word or Excel document to list all the variables. Include three columns:
1. Name of Variables: List the requested variables.
2. Justification: Provide a brief explanation justifying the request for each variable. If the same justification applies to a group of variables, feel free to copy and paste it. Reviewers typically require this to ensure compliance with the Information Practices Act, which mandates that only the minimum necessary data be requested for the study.
3. Usage of Variables: Explain how each variable will be used.

• If you are using any publicly available data sets, please provide a separate list of the variables that will be used from public records and explain their relevance to the study.

Also, please in the “STATE DEPARTMENT DATA/SPECIMENS” section (at the bottom of the 3rd page of the application), Choose the department(s) from which you are requesting data and/or specimens (in the right column) and provide the formal name of the requested database or specimen registry (in the left column).

Thanks.

11/06/2025 • Sussan Atifeh • *Not* Internal • Resolved

Since for addressing the previous comments in this section (left on 11/6/25), you decided not to select the "Data Registry" option, it appears that you are not requesting any state data for conducting this study or for contacting subjects. If that is correct, please confirm in the "Study Procedures" section of the application that no state data will be used for this project.

Thanks.

11/10/2025 • Sussan Atifeh • *Not* Internal • Resolved

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.

Update on 11/10/2025:
To address the comment below, researchers edited the Purpose section of the application by stating, "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."

****

In the "Purpose" section of this application, you mentioned, "Spanish materials and updated instruments will be submitted in later amendments". If you are not including translated recruitment materials in this initial submission, but plan to request approval for translations later through an amendment, please de-select the "Non-English translation required" option now. You can select it when submitting the amendment to request approval for translated versions of the English recruitment materials approved in this initial submission.
Thanks.

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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.

Please name the main site of the study in this section.

• NOTE:
The main site(s) refer to the institution(s) responsible for the primary storage, receipt, and management of study data, as well as for ensuring data security and compliance with relevant regulations. This includes overseeing access controls, data encryption, and privacy safeguards. Typically, this is the Principal Investigator's institution, which houses and manages the servers through which the data is processed.

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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

in the previous section of this application, you mentioned, "Spanish materials and updated instruments will be submitted in later amendments", however, some Spanish documents are attached to this application. Please explain in this section to clarify whether you are requesting approval for translated recruitment materials in this initial submission or you plan to request approval for the translated documents through submitting amendment after the approval of the initial submission.
Thanks.

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Are you requesting approval for all 3 phases of this study in this initial submission? Please briefly clarify.

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If there is not any research staff from CDPH involved in this project, please include a statement in this section confirming that no CDPH research staff will be involved in participant interaction or have access to study data.

11/10/2025 • Sussan Atifeh • *Not* Internal • Resolved

If you are not requesting any state data for conducting this study or for contacting subjects, please confirm in this section that no state data will be used for this project.

Thanks.

11/10/2025 • Sussan Atifeh • *Not* Internal • Resolved

Phase 1 - Formative Research, Focus Groups

Phase 1 qualitative formative research will be composed of focus groups and a check-in survey for three distinct audiences - teens, young adults, and parents/caregivers. The teen audience will include up to 12 focus groups of 4–6 participants each, while the young adult audience will be composed of 8 focus groups of 4–6 participants each, and the parent/caregiver audience will be composed of 6 focus groups of 4–6 participants each (up to N=156).

Virtual focus groups will have no fewer than 4 participants and no more than 6 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 panel to ensure that the virtual platform (Zoom) being used for the virtual groups is installed and functioning properly. While many panelists 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 agency 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.

To account for no-shows, more participants than are needed may be invited to each focus group. We will invite up to 8 participants per focus group in order to seat up to 6 participants in each virtual focus group. Based on the number of potential participants who arrive in the virtual space, on the day of the group, some may have to be turned away. In this case, the participant will still receive the incentive, and they will be informed that the group was overbooked so they are no longer needed to participate. Researchers will inform participants that they are not being excluded because of anything related to their demographic profile.

To check participants into the focus groups, the moderator will have a check-in list provided by the market research recruitment agency with first names and unique ID numbers. The check-in list will be destroyed at the conclusion of each 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 assistant. Participation in the focus group will not exceed 90 minutes for 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 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.

All focus groups will be live streamed privately so that research team members can observe the discussion in real time without participating or interacting with the participants. The live stream will only be accessible to

members of the research team (i.e., CDPH-SAPB and Rescue Agency) and will not be shared with anyone outside of the study. Live streaming the focus groups is a required part of this study, therefore, to be eligible, all participants must 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 study personnel or other members of the project team, through logging onto a virtual platform. This allows for study personnel to participate in real-time observation while ensuring that no interactions between observers and participants occur. The live-stream feed 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. Remote observers will access the live-stream in a room in which only research staff 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 particiants' 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. Immediately following 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. 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.

Audio recoding of the focus group is a required component of this study, therefore, to be eligible, all participants must indicate assent/consent to having the discussion audio-recorded through 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, depenpending on their invidual comfort level.

Participation in the focus group requires all participants' assent/consent to live stream and audio record the discussion. To further protect participant privacy, they will be reminded by the moderator, during the checkin, 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) are the same with the exception of minor differences in timing and activities between audiences. This is indicated in the moderator guides and below (see Attachments: Teen SNT Moderator Guide; Teen EXP Moderator Guide; Young Adult Moderator Guide; Parent/Caregiver Moderator Guide).

Summary of Focus Group Activities, Phase 1:

Technical Check of Zoom Platform
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)

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 use patterns, motivations, risk perceptions, mental health and lifestyle factors, and parental or social influences on attitudes and communication about cannabis.

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

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.

Statement Survey and Fact Discussion (20–25 minutes): The moderator will ask participants to provide their opinion 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.

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.

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 to test which styles, tones and approaches work best.

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

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.

Participants will have the opportunity to provide their contact information if they wish to be contacted for future study activities through the assent/consent forms. This section 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. Participants must provide their email address and/or phone number during their assent/consent to the study, or select the statement 'I prefer not to be contacted for future projects'. Any participants who select the statement above will not be contacted. Participants' contact information will be stored in a password-protected server only accessible to Rescue Agency research staff, separate from any survey responses.

In any follow-up communication, research staff will contact 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 informed assent/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 creative concepts 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 6 participants each across three audiences (i.e., Teens, Young Adults, and Parents/Caregivers) (up to N=126). All procedures (e.g., screening, recruitment, virtual focus groups) will be the same as those discussed 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 messages' and creative materials' 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 values that encourage a health

promotion message. Ultimately, this information will be utilized to inform the educational messaging strategy for youth cannabis prevention.

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:

Check-In Survey: Will assess perspectives and behaviors related to cannabis use among teens, young adults, and parents/caregivers. It covers topics such as use patterns, motivations, risk perceptions, mental health and lifestyle factors, and parental or social influences on attitudes and communication about cannabis.

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 assent/consent to live-stream and audio record the discussion; agreeing to the live stream and audio recording is required for participation.

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.

Brand and Creative Message Testing: This activity is intended to provide insight into the most promising creative concepts for the statewide education campaign and guide refinement of the creative strategy. Sets of preliminary creative concepts designed to tap into the unique values and interests of the audience will be tested. Creative concepts may include video storyboards, which are sketches of videos that focus on a health promotion message, and preexisting ads. For each creative concept, respondents will first respond to a series of Likert-scale statements to preliminarily assess ad likeability, which will then be followed with a qualitative group discussion. The order of the presented creative concepts will be randomized between focus groups to minimize order effects. Additional qualitative discussion will assess participants' preferences for and opinions of each concept, emotional reactions and associations with the concepts, as well as intentions to engage with the concepts.

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

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 6 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. All research protocols established in earlier phases will continue to be followed to ensure participant privacy, data security, and ethical compliance. As the final produced campaign materials 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:

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 assent/consent to live-stream and audio record the discussion; agreeing to the live stream and audio recording is required for participation.

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.

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, respondents will complete 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.

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

Note: In this application we have included certified Spanish translations of the Parents/Caregivers "Consent Form" and "Screener Survey". All other Spanish versions of materials for parents/caregivers (i.e., Parent/Caregiver Check-In Survey, Parents/Caregivers Moderator Guide, and Parents/Caregivers Statement Survey) associated with this protocol will be submitted to CDPH-SAPB following IRB approval of the English materials.

We are also seeking approval for all three phases of research (i.e., Phase 1, Phase 2, and Phase 3) as described above. All research materials for Phase 2 and Phase 3 will be submitted and requested for approval as amendments.

No state data will be used for this project, all data will be collected from newly recruited participants - see page 9 - 10 for audience inclusion criteria, and page 11 for recruitment procedures.

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.

Staff 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 claeaned by 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
CDPH Cannabis_Parents_Caregivers Moderator Guide.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-SAPB Cannabis Protocol 11.11.2025.docx	Protocol
CDPH Cannabis_Parents_Caregivers Check-In Survey.docx	Questionnaires
CDPH Cannabis_Parents_Caregivers Screener Survey_Spanish.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.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

Deleted Attachments: 18 (Most Recent: CDPH-SAPB Cannabis Protocol 11.5.2025.docx on 11/11/2025 3:09 PM ET)

RECORDING

Will audio or video recording occur?

Yes

Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).
As detailed in the assent/consent forms, focus groups will be audio recorded and live streamed, and participants must indicate that they agree to the discussion being recorded and live streamed on the assent/consent form. All interested participants must read and return the signed 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 chose 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 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, 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.

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.

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 6 participants (8 participants will be invited to each focus group with a goal to seat 6)

Young Adult Audience (up to n=48)
18–20 years old
8 Focus Groups with 6 participants (8 participants will be invited to each focus group with a goal to seat 6)

Parents/Caregivers Audience (up to n=36)
30–55 years old
6 Focus Groups with 6 participants (8 participants will be invited to each focus group with a goal to seat 6)

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 6 participants (8 participants will be invited to each focus group with a goal to seat 6)

Young Adult Audience (up to n=42)
18–20 years old
7 Focus Groups with 6 participants (8 participants will be invited to each focus group with a goal to seat 6)

Parents/Caregivers Audience (up to n=36)
30–55 years old
6 Focus Groups with 6 participants (8 participants will be invited to each focus group with a goal to seat 6)

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 6 participants (8 participants will be invited to each focus group with a goal to seat 6)

Young Adult Audience (up to n=18)
18–20 years old
3 Focus Groups with 6 participants (8 participants will be invited to each focus group with a goal to seat 6)

Parents/Caregivers Audience (up to n=12)
30–55 years old
2 Focus Groups with 6 participants (8 participants will be invited to each focus group with a goal to seat 6)

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 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 risk 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, such as avoiding scenarios in which excessive drug use takes place (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 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 negative role models, including 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.

Recruitment will take place across California, comprising a non-representative general cross-section of the target population. Recruitment will be overseen by Rescue Agency and primarily conducted by one or more vetted professional market research recruitment agencies, who have extensive experience recruiting youth and adult populations. Rescue Agency will support recruitment or coordination as needed. Various methods of recruitment will be utilized to reach all three target audience segments, including:
Recruitment via Market Research Panel – The recruitment agency will draw from its own existing database of individuals interested in research participation, who have voluntarily signed up to participate in research. Recruitment agencies typically have basic demographic information of participants, including sex, age, and languages spoken. As the list of panelists is proprietary to the recruitment agency, contact information (e.g., email addresses, phone numbers) for their panel members will never be provided to the Rescue Agency research team. For teen recruitment, recruitment agencies may reach out to parents of teens in their panels, introduce the current study and its purpose, and obtain initital parental permission for their teen to participate in the screener survey.

Recruitment via Snowball Sampling – Recruitment may also include snowball sampling in which individuals who have participated can forward the Screener Survey link to interested friends or acquaintances. An interested friend or acquaintance can then complete the online Screener Survey to determine if they are eligible to participate.

Recruitment via Community-based Organizations – Recruitment may also be conducted through outreach to community organizations, clubs, and other service groups. They would be asked to distribute the online Screener Survey link to interested teens, young adults, and parents/caregivers of youth living in the state of California. Those recruited in this manner will complete an online version of the Screener Survey to determine eligibility.

Recruitment via Social Media Advertisements – Participants may be recruited through the use of paid social media advertisements. Participants will see social media ads on a social media platform (e.g., Facebook, Instagram). Individuals recruited in this manner will be connected with recruitment agencies to complete an online version of the Screener Survey to determine eligibility. For participants under the age of 18, advertisements will be

designed and targeted in accordance with platform policies and ethical guidelines for engaging minors (e.g., recruitment and consent process includes parental permission and child assent; no identifying information from minors will be collected before parental consent is obtained). Individuals who indicate that they are under 18 will be asked to provide their parents contact information to obtain parental consent for their teen to participate in the study (see Attachment: Teen Parental Verbal Consent Script). Once parental permission is obtained, teens will be directed to complete the Screener Survey with appropriate parental or guardian consent procedures in place prior to participation. Recruitment materials will be age-appropriate and will clearly state any parental consent requirements.

Recruitment of participants may occur up to five weeks in advance of focus groups.

Screening

Market research agencies 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, confirm parental interest for their teen to participate in the study, and obtain parental permission for their teen to participate in the screener survey, after which the youth will be sent an online version of the Screener Survey so that they may independently complete the Screener Survey.

Self-administered – In the event that phone screening is not feasible, recruiters will send a link to an online version of the Screener Survey to youth or adults via email or text for the youth or adult to complete online at their convenience. The online Screener Survey will be hosted by the market research recruitment agencies using a proprietary online survey system that will be compatible or use on smartphones, tablets, or computers. For teen participants, the recruitment agency may contact parents 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. 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 not shared with anyone outside of the research team. 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 if they are eligible and invited to participate in a focus group.
Following recruitment activities, study staff 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, pg. 14). 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 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 consent form for those under the age of 18 for their parent to sign (see Attachments: Teen Parental Consent Form; Teen Parental Verbal Consent Script).

Attach copies of all recruitment materials.

CDPH Parents Recruitment Flyer.pdf	Recruitment Materials
CDPH Teen Recruitment Flyer.pdf	Recruitment Materials
CDPH YA Recruitment Flyer.pdf	Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.
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 physicians 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 are not comfortable answering. 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). Use will be assessed as either experimenters or susceptible non-triers and 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 time 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”

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

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 $125 incentive to encourage attendance, cover costs associated with participation (e.g., data fees), and as a "thank you" for their time. An additional $10 will be provided to teens for each participant they refer through snowball recruitment. Participants from the young adult 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. An additional $25 will be provided to young adults and parents/caregivers for each participant they refer through snowball recruitment. 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).

The incentive will be distributed 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 is removed from a focus group for any reason, 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 for participation in the focus groups. During the recruitment and 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.
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 substance 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 assent/consent form 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 assent/consent stage.

(2) Prior to participating in the focus groups, research staff will verbally explain to participants that they can choose not to respond to any survey questions or focus group questions at any time. Therefore, if participants feel discomfort they can simply skip those questions, decline to respond altogether, or stop participating. Focus group participants will be informed by email, through the 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 have the choice of submitting the check-in survey and/or qualitative data they have already provided, or having their data removed. 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) No contact information will be asked from or made available from participants who participate in focus groups. 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 section 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 assent/consent forms, or select the statement 'I prefer not to be contacted for future projects.' Any participants who select the statement above will not be contacted. In the case of teen participants who are interested in recontact, we will collect their parents contact information via the parental consent forms, and no direct contact information of teen participants will be collected. Contact information provided in the Voluntary Contact Information portion of the assent/consent forms will be removed from the analytical dataset prior to analysis, and will be stored separately in a password-protected computer folder accessible only by Rescue Agency staff. This contact information will only be used to contact interested individuals for future research opportunities.

While we minimize the collection of personally identifiable information (outside of voluntary contact information for recontacting participants), names are collected on consent forms. While we will store digital copies of the electronically signed consent forms in secure files at Rescue Agency, as with any research study, there is a chance that confidentiality could be compromised. As such we have also taken steps to minimize the collection of identifying information, limit the length of time that identifying information is retained, and ensure a high level of digital security, reducing likelihood of a confidentiality breach.

Unique ID codes 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 agency to use in all check-in surveys and focus group discussions.

For focus groups, it will be necessary for researchers to have access to a grid that includes the participant's first name 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 provided to Rescue Agency by the recruitment agency that includes the participant's first name and unique ID code through a shared secure drive. This will allow Rescue Agency staff to confirm that all electronically signed 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 staff 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.

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.

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 project team members to observe and analyze the focus groups. Access to live-streaming will be granted by invitation only through a unique link that will only be shared with research team staff 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 assent/consent to the live steam and audio recording in the 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.

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). 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.

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

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

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

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

HIPAA IDENTIFIERS

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

Name
Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
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 staff 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 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 project 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 project 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 data from this study may be used in future research and/or shared with other researchers, 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 assent/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.

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 other researchers, 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.

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 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 individuals, to confirm the educational messages are effective. Finally, the final campaign materials will be tested with approximately N=54 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.

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 project team members 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

Would you please update the attached Data Security Letter (DSL)? The link in the attached letter does not open the correct page.

For your convenience, you can access the relevant resources using the links below:

• Data Security Letter Template
https://www.cdii.ca.gov/wp-content/uploads/2024/03/Data-Security-Letter-Template-Accessible.pdf

• Data Security Requirements
https://www.cdii.ca.gov/wp-content/uploads/2023/04/Data-Security-Requirements-2012-04-20.pdf

11/06/2025 • Sussan Atifeh • *Not* Internal • Resolved

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

Deleted Attachments: 1 (Most Recent: CDPH Data Security Letter - Signed_2025.pdf on 11/07/2025 7:12 PM ET)

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 assent/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 project 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 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 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 that verbal consent be used 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 Surveys; 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, individuals who qualify will be read the consent form and the participant bill of rights by the recruiter. At the conclusion of the verbal consent form, the participant indicates if they would like to participate.The participant is then emailed a copy of the consent form and the participant bill of rights by the recruitment agency, which can be signed electronically. 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).

The signed consent forms for all audiences are automatically saved in a secure file in Rescue Agency’s 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 signatures on the consent form and confirming whether the participant has consented to audio recording/ live-streaming.

For Youth (under the age of 18)
The procedures for youth are similar to the above, with these additional caveats.

Within the Screener Survey, youth will be requested to provide parent/guardian contact information for notification and permission purposes. Youth who complete the Screener Survey online will be sent a link (via text or email) to the consent and assent materials that includes, a Parent/Guardian Consent Form, and a Participant Assent/Consent Form (see Attachments: Teen Assent Form; Teen Parental Consent Form).
Youth will be asked to review and share the Parental Consent Form with their

parent(s)/guardian(s). The form will provide clear and simple instructions for how a parent/guardian can provide or reject consent in writing. Recruiters will inform potential participants that the Parent/Guardian Consent Form is for their parents'/guardians' review and that they must provide the signed Parental Consent Form at least 24 hours prior to starting any research related activities outside of screening. In instances where a parent/guardian may have signed the consent form prior to screening, their consent will extend to the focus group participation. If a participant forgets their form and a parent/guardian is not present, verbal consent may be obtained from a parent/guardian over the phone (see Attachments: Teen Parental Verbal Consent Script). If verbal parent/guardian consent is received, the recruiter calling to obtain parent/guardian consent will fill out all relevant sections of the Parental Consent Verbal Script, including youth name, parent/guardian name, relation to youth, phone number for consent confirmation, date, time of call, and the recruiter's and a witness' signature. If a parent/guardian chooses not to give consent for their child to participate, the recruiter will document this decision on the Parental Consent Verbal Script and the youth will not be eligible for participation.

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.

CDPH Cannabis_Parents_Caregivers Consent Form.docx	Consent Form
CDPH Cannabis_YA Consent Form.docx	Consent Form

Deleted Attachments: 5 (Most Recent: CDPH Cannabis_YA Consent Form_11.05.25.docx on 11/06/2025 3:17 PM ET)

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.docx	Consent Form

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

Deleted Attachments: 1 (Most Recent: Declaration of Certified Translation.pdf on 11/07/2025 7:20 PM ET)

ASSENT PROCEDURES

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

See instructions and examples on the CPHS website.

Informed assent from youth participants (ages 13–17) will be obtained and documented through a formal electronic assent process that occurs only after verified parental permission. Recruitment vendors may contact parents within their existing participant panels who have a teen in the eligible age range to ask whether they and their teen would be interested in the study; if interested, the teen will be sent the online screener survey and, if determined eligible, the parent will then receive the Parental Consent Form and the teen will receive the electronic Participant Assent/Consent Form to sign and return to the research team before participating in any study activity. As part of the screener process outside of vendor panels, youth may also provide contact information for their parent/guardian so that written or verbally documented parental consent can be secured prior to any participation beyond screening. Once parental consent is received, the youth reviews and signs the assent form to indicate their voluntary willingness to take part in the research activities. The assent form clearly explains the purpose of the study, voluntary participation, required audio-recording and live-streaming, confidentiality protections, risks, and the option to withdraw at any time. Signed assent forms are automatically stored in Rescue Agency’s secure electronic file system, and research staff confirm receipt of both parental consent and youth assent before the youth is admitted into any focus group session. If a parent/guardian declines permission, or if youth do not assent, the youth is not 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.

CDPH Cannabis_Teen Parental Consent Form.docx	Assent Forms
CDPH Cannabis_Teen Parental Consent Verbal Script.docx	Assent Forms
CDPH Cannabis_Teen SNT & EXP Assent Form.docx	Assent Forms

Deleted Attachments: 3 (Most Recent: CDPH Cannabis_Teen SNT & EXP Verbal Consent Script_11.05.25.docx on 11/06/2025 3:19 PM ET)

HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

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

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

Signed Tuesday, November 11, 2025 2:45:23 PM ET by Danny Azucar, PhD, MPH

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

Responsible Official Signature
- Submitted 11/06/2025 4:31 PM ET by Dawnyéa Jackson, PhD

Responsible Official Signature

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

Yes, ready for submission to IRB.

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

Signed Thursday, November 6, 2025 4:31:51 PM ET by Dawnyéa Jackson, PhD

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

Notify IRB for Pre-Screening
- Submitted 11/12/2025 11:49 AM ET by Sussan Atifeh

Internal IRB Screening

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

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

Yes

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

CPHS

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

Full Board Minimal Risk

Please provide a rationale for your level of review preliminary determination
CPHS Chairs confirmed this project should be discussed in the December 5, 2025, 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

December

Assign to cycle year
2025

Load into IRBManager (Initial Submission)
- Submitted 11/12/2025 11:50 AM ET by The System

Chair Review and Full Board Set-Up
- Submitted 11/12/2025 11:52 AM 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
This project has human subjects' contacts components and CPHS Chairs confirmed it should be discussed in the December 5, 2025, Full Board Meeting.

Assign SME to study

Laura Lund, MA

Enter the meeting date for this project

12/05/2025

SME Review

SME review

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

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

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

No answer provided.

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