

View xForm - Project Application v6

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

Data entry

- Submitted 05/02/2025 3:31 PM ET by Annu van Bodegom

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

June 2025 cycle.

1. _____ HSC Project _____

No request for state data.

This project is funded by CalHHS__A LOS from CalHHS is attached.

A DSL from Mathematica is attached.

05/08/2025 • Sussan Atifeh • Internal

Researchers from Mathematica have submitted this study (Caregiver, Youth & Young Adult Focus Groups) which is part of the California Children and Youth Behavioral Health Initiative (CYBHI), funded by CalHHS under contract 2022-197-CYBHI and led by Mathematica. This study aims to evaluate CYBHI's impact by conducting 30 focus groups with youth, young adults, and caregivers across California to examine how communities have used CYBHI funding to address behavioral health disparities. Importantly, the study does not request or use any state data to identify or contact participants; instead, recruitment is conducted directly through CYBHI-funded community organizations. The findings will be summarized in the Community Spotlight Report, publicly available on the CYBHI website, and will inform policymakers about successes, gaps, and areas for improvement in behavioral health services.

05/09/2025 • Sussan Atifeh • Internal

Hi Dr. Dickey!

This project is one of three related studies submitted by Mathematica as part of the Children and Youth Behavioral Health Initiative (CYBHI). While submitted separately, all are funded by CalHHS and share similar goals. This project involves focus groups or interviews and mostly they are working with de-identified and aggregated state data. Please assess whether the project qualifies for exemption or a "Not research" determination and flag if you believe it should be reviewed under a different pathway by submitting it via an "Exempt" or "Not Research" application.

thank you.

05/12/2025 • Sussan Atifeh • Not Internal

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

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Dan Friend, Ph.D

Email: DFriend@mathematica-
mpr.com

Business: (202) 264-3474

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

Mathematica Policy Research

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

Chicago

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

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

Illinois

Attach a copy of the PI's Curriculum Vitae.

Dan Friend_CV.docx PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

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

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

Vanessa Quince, Ph.D

Email: VQuince@mathematica-
mpr.com

Business: (206) 539-5817

Joelle Atere-Roberts, Ph. D

Email: JAtereRoberts@mathematica-
mpr.com

Business: (410) 907-0920

Attach a copy of each Co-PI's Curriculum Vitae.

JAtere_Roberts_CV.docx Co-PI Curriculum Vitae

VQuince_CV.docx Co-PI Curriculum Vitae

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.

Annu van Bodegom

Email: AvanBodegom@mathematica-
mpr.com

Business: (609) 297-4682

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.*

Rick McManus, MPP

Email: RMcManus@mathematica-
mpr.com

Business: (202) 912-1027

OTHER RESEARCH STAFF

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

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

Haley McCrary, MPH

Email: HMcCrary@mathematica-
mpr.com

Business: (617) 588-9528

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

False

Project Information

SUBMITTER

Application completed by:

Annu van Bodegom

Email: AvanBodegom@mathematica-
mpr.com

Business: (609) 297-4682

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).

Evaluation of the California Children and Youth Behavioral Health Initiative (CYBHI): Caregiver, Youth & Young Adult Focus Groups

PROJECT SITE

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

Mathematica Policy Research, Inc.

STUDY PROCEDURES

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

Focus Groups
Program Evaluations
Recruitment-Participant

TYPE OF RESEARCH REQUEST

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

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

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

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

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

Common rule/Human subjects

PROJECT TYPE DETAILS

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

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

Minimal Risk
Consent form
Assent form

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_CLS.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.

CalHHS

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

08/01/2025

ANTICIPATED PROJECT END DATE

06/30/2026

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.

In July 2021, California established the five-year, \$4.4 billion Children and Youth Behavioral Health Initiative (CYBHI) to transform the way California supports the mental, emotional, and behavioral health and well-being of children, youth, and families. CYBHI seeks to support comprehensive change in the education, health care, and other child-serving systems to deliver equitable, appropriate, timely, and accessible screenings, services, and supports for emerging and existing behavioral health needs for all children and youth ages 25 and younger. The California Health and Human Services Agency (CalHHS) has funded a multi-year mixed-methods evaluation to inform future decisions by policymakers based on what the CYBHI accomplished and what was learned during its implementation.

As part of the evaluation, we will develop a product, the Community Spotlight Report, that focuses on communities, for example racial and ethnic minorities, gender minorities and other populations, facing disparities in California's behavioral health system. We will combine quantitative data with personal anecdotes to produce findings. We will amplify community voices on behavioral health, highlighting their strength and resilience as well as the challenges they encounter. The goals of this product include identifying bright spots of CYBHI implementation in addressing disparities through focusing on how communities have been able to leverage CYBHI funding, and to illuminate the remaining gaps across different settings. This is the key product in Mathematica's evaluation to understand and showcase impacts for intended beneficiaries.

We will conduct 30 focus groups with youth, young adults, and caregivers across California. The focus groups will gather important information related to the experiences of participants impacted by California's behavioral health system. Focus group topics will include information related to participation in CYBHI funded activities, navigating the behavioral health ecosystem, system-level support & collaboration, and successes, challenges & recommendations. The analytic approach will involve summarizing coded data in matrices to identify key patterns and themes in participants' response.

Our key audience is CalHHS and the public including California residents and individuals receiving CYBHI services, and anyone interested in mental health policy. The Community Spotlight Report will be published via the CYBHI evaluation website.

MAJOR RESEARCH QUESTION

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

The focus group data collection described in this IRB application will help address these specific research questions:

- How do youth and families experience the behavioral health system?
- How have communities leveraged CYBHI funding?
- How do youth and families experience the accessibility and navigability of behavioral health services?
- How has CYBHI influenced collaboration across sectors to improve care for youth and families?
- How is CYBHI redefining behavioral health services to include diverse and innovative practices??
- What are the remaining equity gaps in funding?

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

Purpose. The focus groups are intended to gather information about how youth, young adults, and caregivers in key populations impacted by behavioral health disparities have leveraged CYBHI funding for impact. It will also help identify and elevate remaining equity gaps.

Identify Participants. Mathematica will partner with community organizations who received funding for CYBHI services. Our team will share a recruitment letter with organizations associated with CYBHI to share with their networks of youth and families to request their partnership in recruiting participants for one or more of the sample groups. The recruitment letter is saved as an attachment called "Partner Organization Recruitment Letter." Our team will also solicit a recruitment flyer and email to the partner organizations to support focus group recruitment. We include the recruitment flyer and letter in the attachments called "Language for Listening Session Recruitment Flyer" and "Participant Recruitment Emails." Organizations can decline to participate without any impact on their role with CYBHI. If they choose to participate, they can additionally choose to passively share the recruitment materials or participate in active targeted recruitment. The organizations that choose to participate in active targeted recruitment will be compensated as outlined in a signed Memorandum of Understanding.

To mitigate potential conflicts of interest and power dynamics between CYBHI-funded organizations and prospective participants, we will clearly communicate that participation in the focus groups is entirely voluntary. Partner organizations will not apply pressure or influence individuals' decisions to participate, and services or support received from these organizations will not be impacted by an individual's choice to participate or decline. Additionally, organizations will not be informed of which specific individuals choose to participate in the study, and participant identities will not be shared back with the recruiting organizations. These measures will be included in training and guidance materials shared with partner organizations to ensure ethical recruitment practices.

The recruitment flyer will include a link to an online screening questionnaire participants can complete to express their interest in the focus groups. We will use the online screener to collect basic demographic information and information related to CYBHI services to help construct focus groups representing a range of identities and experiences. We will ask participants if they can participate in virtual focus groups with webcams and virtual meeting software or whether they will need to participate by phone only. For youth ages 14–17, a parent or guardian will be required to complete the online screener on the youth's behalf. Young adults (ages 18–25) and caregivers will complete the screener for themselves.

After completing the screener, we will contact selected participants via email to schedule the focus groups. Alongside the focus group confirmation email, we will send the consent forms for parents/guardians to complete on behalf of the youth ages 14-17, and for young adults caregivers to complete for themselves. The participants will be asked to send the completed consent forms via email in advance of the scheduled focus group. All participants will be required to have a completed consent form before participating in the focus groups. Participants will also be asked to provide verbal assent at the start of the focus group to confirm their willingness to participate. We include the online screening questionnaire and consent forms in the attachments called "Online Screener_submission" and "Consent Forms_submission".

The online screener will be primarily administered electronically, but we will supply paper copies to partner organizations to administer to families who prefer paper or cannot access the electronic screener. The information from the screener will be sent to Mathematica directly electronically or hand collected through certified mail. For the hand collected forms, the respondent will complete the screener, put it in an envelope and give it back to the organization to ship back to Mathematica via FedEx. Similarly, we will offer a paper version of all consent forms that can be returned via mail. The partnering organizations will not have access to the responses from the screener or consent forms. Mathematica will use the responses from the screener to determine eligibility and group participants for focus groups based on geographic regions, demographic information (for example, age, race/ethnicity), availability, and behavioral health experiences.

The recruitment flyer, recruitment letter, and screener will be available in both English and Spanish. For translation of the materials, we will use Community Language Cooperative (CLC), a group that has supported interpretation and translations services for the CYBHI evaluation advisory group meetings. The CLC will also translate the discussion guide to Spanish. We plan to send the recruitment documents, caregiver protocol and screener documents translated once we receive IRB approval for the English language screener and recruitment documents. We will then plan to upload the translated documents to the CPHS site with an amendment to this IRB application.

We plan for approximately 30 focus groups with approximately 180-240 total youth, young adults, and caregivers. Each focus group will include six to eight participants. We will create groups within each of 5 regions in California: (1) Superior; (2) Central; (3) Greater Bay Area; (4) Southern; and (5) Los Angeles. Within each region we will aim to hold separate focus groups with each of 2 different groups:

- Youth and young adults ages 14-25
- Caregivers of children/youth ages 0 to 25

Additionally, for each of the caregiver groups, we will offer another session per region in Spanish to accommodate caregivers whose primary language is Spanish. Spanish is the most widely spoken non-English language in California, and a significant proportion of the California's population identifies

as Latinx/Hispanic. Current resource constraints—including budget, staffing, and translation/interpretation capacity—limit our ability to offer sessions in additional languages. However, we will monitor interest from non-Spanish-speaking populations and explore alternative accommodations as feasible, such as translated materials or follow-up interviews with interpreters if needed.

Conduct Focus groups. Once participants are determined to be eligible, they will be scheduled for a focus group by the Mathematica recruitment team. Mathematica will conduct up to 30, 90-minute virtual focus groups in the fall of 2025 with youth and young adults (ages 14 to 25) as well as with caregivers of children and youth (ages 0 to 25 years) in California. Each focus group will include approximately 6-8 participants, for a total of 180 to 240 participants across the six focus groups. We will prioritize virtual focus groups to accommodate participants across the state by reducing the travel and time burden on participants. If we receive sufficient interest for an in-person focus group within a specific geographic region and respondent group (e.g., caregivers in a particular county), we will explore the option of holding one or more sessions in person. In such cases, we will coordinate with partner organizations to identify an appropriate, accessible, and private space to host the session.

We will use skilled facilitators, web-based technology, and interactive online exercises, such as polls, to foster engagement in a virtual space. To create an inclusive and accessible environment, the facilitator will introduce themselves and visually describe themselves for people who are blind or have low vision (e.g. hair color, gender, glasses, what you're wearing, race/ethnicity, etc.). The facilitator will also share their pronouns and will describe the virtual or physical space as needed (e.g., who is present, layout, visual materials shared on screen). Participants will be presented with assent language before beginning the focus group and may choose to skip any question or withdraw from the group at any time.

We will implement several strategies to support the emotional well-being of participants, especially youth under the age of 18. All facilitators will be trained in trauma-informed and youth-centered approaches. This training will emphasize creating a safe, respectful environment; recognizing signs of distress; and responding supportively and appropriately to emotional reactions. During each focus group, a dedicated co-facilitator will monitor participant engagement and emotional cues (e.g., visible distress, withdrawal). The co-facilitator will conduct real-time, emotional check-ins if needed. These check-ins may occur via private chat (for virtual sessions) or one-on-one conversation (for in-person sessions). At the beginning of each session, facilitators will set the tone by acknowledging that discussions may bring up strong feelings and encouraging participants to step away or take a break if needed. At the end of each session, facilitators will review available resources, reinforcing that participants' feelings are valid and support is available. A licensed mental health clinician will be available on standby during each focus group session to provide immediate consultation to the facilitator team if a participant exhibits acute distress. If needed, the clinician may engage directly with the participant or assist in making a warm referral to appropriate services. Facilitators will emphasize that participation

is completely voluntary, and that youth may choose to skip questions, pause, or withdraw from the group at any time without consequence.

The focus groups will gather important information related to the experiences of youth, young adults, and caregivers in California. More specifically, some of the topics discussed during the focus groups will include information related to participation in CYBHI funded activities, experience participating in CYBHI funded strategies, navigating the behavioral health ecosystem, system-level support & collaboration, cultural responsiveness & community defined practices, and successes, challenges & recommendations. The proposed focus group schedule is as follows:

Schedule: ~90 minutes

1. Introduction and orientation, group norms, how to participate, and icebreaker (15 minutes)
2. First discussion - Participation in Behavioral Health Services (18 minutes)
3. Second discussion - Navigating the broader Behavioral Health system (18 minutes)
4. Third discussion – Meeting Cultural Needs (18 minutes)
5. Fourth discussion - Biggest Successes, Challenges, and Future Recommendations (18 minutes)
6. Quick thank you - (3 minutes)

We include focus group discussion guides for the youth and young adults and caregivers in the attachments called “CLS_Youth Listening Session Protocol” and “CLS_Caregiver Listening Session Protocol.”

The focus group will not include any questions about specific behavioral health conditions or questions about self-identity, such as sexual orientation or gender identity. However, given the small psychological risk related to the topics, we will also provide the information for contacting the 9-8-8 Suicide & Crisis Lifeline and SAMHSA Find Treatment service at the beginning of the session should anything about the discussion trigger a desire for information on connecting to behavioral health supports. Both services are available 24 hours a day, year-round, in both English and Spanish.

We have project staff from Mathematica and our partner, the University of California Los Angeles, who are native Spanish speakers and will review the Spanish translate discussion guides for readability and conduct the Spanish focus groups. During data collection, with respondents’ permission, the evaluation team will record all focus groups. This will ensure complete and accurate data. We will include written language about recording the focus groups in the consent forms. The transcripts will form the dataset for qualitative analysis. We will have transcripts in Spanish translated to English by CLC.

To reimburse focus group participants, we will provide each participant with a \$50 VISA gift card via email.

Data Analysis:

We will identify common patterns and themes across the different experiences and perspectives reported by focus group participants. We will

develop a codebook to organize the data by domain to understand themes across groups and work collaboratively to ensure consistency of coding. We will use qualitative software to generate themes. The analytic approach will involve summarizing coded data in matrices to identify key patterns and themes in enrollees' responses. By drawing on the patterns and themes that emerge across interviews, we will develop a narrative report of findings that address the research questions.

When we present and publish findings, we will likely use illustrative quotes from the focus groups, but we will redact any names, references to specific schools or geographies, and any other potentially individually identifying information from any quotes.

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.

Consent Forms_submission.docx	Consent Form
CLS_Caregiver Listening Session Protocol_submission.docx	Protocol
CLS_Youth Listening Session Protocol_submission.docx	Protocol
Language for Listening Session Recruitment Flyer_submission.docx	Recruitment Materials
Online Screener_submission.docx	Recruitment Materials
Participant Recruitment Emails_submission.docx	Recruitment Materials
Partner Organization Recruitment Letter_submission.docx	Recruitment Materials

RECORDING

Will audio or video recording occur?

Yes

Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).

We will record all focus groups using a web-based meeting platform. The video and audio recordings will be maintained as electronic copies and kept in a restricted folder on our secure password protected network drive. We will save video and audio recordings with filenames that will not include participant names when stored on our secure server or when shared with the transcription service. During the focus groups, we will only use participants' first names so the recordings will not capture the last names of any participants. We will ask each respondent for permission to use their first name when reading the consent script.

We will have the audio recordings transcribed by a transcription service. We will use a secure file transfer site to deliver the electronic audio recordings of the focus groups for transcription. We will receive transcripts through secure transfer and save them to our secure folder with restricted access. We will then remove all first names included in the transcripts and maintain the transcripts within the secure drive. We will require the transcription service to delete the audio recordings and transcripts within 90 days of our receipt of the transcripts. Video recordings will not be shared outside of the evaluation team and will never be used for public dissemination or reporting. Access to recordings will be strictly limited to essential research staff who are trained in human subjects protections and data confidentiality protocols.

Video and audio recordings will be retained only as long as necessary to complete transcription, data verification, and analysis. We will erase the video and audio recordings from the web-based meeting platform as soon as possible after completing each focus group and transferring the recordings to a restricted access folder within our secure password-protected network drive. At the end of our study, we will then destroy the recordings within this folder and ask our information technology services team to provide a certificate of destruction. We will also require our transcription service to destroy the audio recording and all copies of the transcript in their possession and send written confirmation of data destruction.

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.

Not applicable

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.

In the fall of 2025, we will conduct data collection for the focus groups in California. We will conduct up to 30 focus groups across the each of the 5 regions of California. For each focus group, we will recruit six to eight participants, for a total of no more than 240 participants across the 30 focus groups.

We identified 2 different groups of participants to include in the focus groups within each region for up to 30 focus groups:

- Youth and young adults ages 14 to 25
- Caregivers of children/youth ages 0 to 25

We aim to recruit a diverse sample of participants in key communities such as racial and ethnic minorities, gender minorities, and other communities impacted by California's behavioral health system. For example, we may oversample to include youth, young adults, and caregivers in the following groups based on existing literature and data on behavioral health disparities in California:

- Participants who identify as Black, American Indian or Alaska Native, Asian, Native Hawaiian and Pacific Islander, or Hispanic/Latin(x)
- Participants who identify as part of the LGBTQ+ community
- Participants who identify as female or non-binary
- Participants residing in rural areas

RATIONALE

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

The rationale for studying the requested group of participants is to obtain data that are more in-depth and timelier than those currently available from other existing data sources on behavioral health experiences and perspectives from youth, young adults, and caregivers in California. These participant groups will help illuminate how CYBHI is being implemented and experienced by its intended beneficiaries. Additionally, we are seeking the specific experiences of key communities facing behavioral health disparities to understand how they have leveraged CYBHI funding to drive change.

The rationale for the caregiver focus groups is to obtain richer or more in-depth context on the child/youth's behavioral health experiences compared to interviewing the children and youth themselves – who may not be of age to share details of their experience. The rationale for the youth and young adult focus groups is to capture the perspective of youth and young adults directly who can articulate their personal experiences in the focus group setting.

The focus group data will serve as a complementary data source that enhances and contextualizes findings from other components of the evaluation.

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.

While waiting for IRB approval, we will begin to identify potential organizations. We will not initiate recruitment until after we receive IRB approval. The CYBHI evaluation team has a list of community-based organizations that have participated in other data collection activities. We plan to leverage their relationships to identify potential participants. We will reach out to these organizations to discuss how we will partner together for recruitment. We will assess whether there are any gaps in our sample; and if needed, will reach out to individuals already engaged in CYBHI activities, such as the CYBHI Evaluation Advisory Group, to help us to identify additional participants.

Organizations can decline to participate without any impact on their role with CYBHI. If they choose to participate, they can additionally choose to passively share the recruitment materials or participate in active targeted recruitment. The organizations that choose to participate in active targeted recruitment will be compensated with a \$100 VISA electronic gift card for support with recruiting and engaging with participants for the focus groups. In addition to partnering with Mathematica to recruit for the focus groups, the partnering organization can attend the focus group to lead the introduction, conduct an icebreaker and provide closing remarks.

We will use a mix of convenience and purposive sampling to identify and recruit respondents from across the state and with specific identities (e.g., age, geographic location, race and ethnicity, and gender identity). This sampling will enable us to efficiently collect data from a range of respondents representing diverse voices and to understand the breadth of experience across youth, young adults, and caregivers while also minimizing respondent burden (e.g., lowering the time investment requirement).

Additionally, our team will provide a recruitment flyer to organizations associated with CYBHI, which they can share with their networks of youth and families to support recruitment for one or more of the sample groups. The flyer will include a description of the CYBHI evaluation, the purpose of the focus groups, the length (90 minutes for focus groups), and include contact information for our staff (Toll Free Number: 855-743-8476 and CYBHI email: CYBHIEvaluation@mathematica-mpr.com) so that participants can contact us if they would like to participate. On the flyer, we will explain that participation is voluntary and that we are providing incentives (a VISA gift card). We include the flyer in the attachment called "Language for Listening Session Recruitment Flyer."

Once the respondent agrees to participate, we will coordinate a time for the virtual focus group. The Mathematica team will send a calendar invitation via email that includes the date and time of the focus group, access information for the web-based meeting platform, and an attachment of the consent script as a PDF. The consent script includes an explanation of what participation involves, the risks and benefits, and that participation is voluntary and confidential, and the respondent can stop the session at any time and refuse to answer any of our questions. We will send a reminder email 1 day before the focus group is scheduled to take place, re-sharing the details of the focus group (date, time, access information, consent script).

We will ask caregivers to provide their consent on the consent form as well as their verbal consent before we begin recording the focus group. For minor participants, parents/guardians will be asked to complete the active consent form prior to the youth being assigned to a focus group. We include the consent forms in the attachment called "Consent Forms" and the assent script in the attachment called "CLS_Youth Listening Session Protocol and CLS_Caregiver Listening Session Protocol."

The recruitment materials for the focus groups are included as attachments.

Attach copies of all recruitment materials.

CLS_Caregiver Listening Session Protocol_submission.docx	Recruitment Materials
CLS_Youth Listening Session Protocol_submission.docx	Recruitment Materials
Consent Forms.docx	Recruitment Materials
Language for Listening Session Recruitment Flyer_submission.docx	Recruitment Materials
Online Screener_submission (1).docx	Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

Yes

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

Selection Criteria: Reside in California (by region)

Rationale for Selection: Want a diverse representation of participants across the following regions: Superior, Central, Greater Bay Area, Southern Los Angeles

Selection Criteria: Youth and young adults (ages 14-25)

Rationale for Selection: Want the specific perspectives of participants who currently or previously experienced changes in the behavioral health landscape in California because of CYBHI implementation.

Selection Criteria: Caregivers (children and youth ages 0-25)

Rationale for Selection: Want the specific experiences of caregivers of children and younger youth who may have or currently experience changes in the behavioral health landscape in California because of CYBHI implementation. Each of the caregivers' groups will be offered in separate English and Spanish groups.

Selection Criteria: Demographics

Rationale for Selection: Want a diverse representation of California residents. We will not exclude participants based on their demographic characteristics, such as gender identity, sexual orientation, family income, immigration status, disability, tribal affiliation, family structure, and justice and/or child welfare involvement.

Selection Criteria: Primary language

Rationale for Selection: Most focus groups will be conducted in English. Additional sessions will be conducted for caregivers whose primary language is Spanish.

If an individual expresses interest in participating but does not enroll in the study, no data will be collected or retained about that individual beyond what is necessary for initial eligibility screening. Any screening information collected will be used solely to determine eligibility and will be securely stored and then deleted within 30 days if the individual does not participate. No identifiable information about individuals who do not enter the study will be used in the research, included in the analysis, or shared with any third parties. Their decision not to participate will have no impact on any services they receive or their relationship with partner organizations or CYBHI-funded

programs.

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.

Focus group participants will receive a \$50 electronic VISA gift card (or via mail if they do not have an email).

Interested organizations will be compensated based on their level of involvement with recruiting and engaging with participants for the focus groups. The compensation for organizations partnering with us to recruit participants will be \$100 honorarium as an electronic VISA gift card.

The \$50 electronic VISA gift card to participants and partnering organizations will be sent via email or mail 5-10 business days after completing the focus groups.

STUDY DURATION

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

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

The entire duration of the study is expected to be from August 2025 until June 2026. The focus groups are expected to begin in August 2025 and end by December 2025. Focus group participants will each participate in only one focus group; each focus group will last approximately 90 minutes; total approximate time commitment for focus group participants is 90 minutes, plus about 10 minutes to complete the online screening questionnaire and consent forms and time to travel to focus groups if we hold them in person. We estimate a total of two to two and a half hours for focus group participants including the time for completing screening and consent forms and traveling to focus group locations (if in person).

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.

The focus group questions will ask about perceptions and experiences regarding behavioral health but not about specific diagnoses, sites of care, or other potentially identifying information. Participation in the focus group is voluntary, adult respondents will be presented with consent language before participating in the focus group, and youth respondents will be presented with assent language before beginning. Respondents can choose to skip any question or stop at any time. We do not ask youth any questions about specific behavioral health conditions or questions about self-identity, such as sexual orientation or gender identity. However, given the small psychological risk related to the topics, we will also provide the information for contacting the 9-8-8 Suicide & Crisis Lifeline and SAMHSA Find Treatment service at the beginning of the session should anything about the discussion trigger a desire for information on connecting to behavioral health supports. Both services are available 24 hours a day, year-round, in both English and Spanish.

The other risk to survey respondents is inadvertent risk of loss of confidentiality. Mathematica's standard security procedures minimize this risk. At Mathematica, all records containing personally identifiable information (PII), such as names, addresses, and emails, are kept on secure password-protected encrypted data storage systems within actively monitored network firewalls. All data transfers from web-enabled devices (PCs and laptops used for survey administration) to the main servers are protected by data encryption and a network firewall. We will maintain the confidentiality of respondents' specific responses. Participation is voluntary. Respondents may choose to not answer any of the questions. During the focus groups, we will only use participants' first names so the recordings will not capture the last names of any participants. We will ask each respondent for permission to use their first name when reading the consent script. We will remove all first names included in the transcripts and maintain the transcripts within the secure drive. Mathematica will inform participants of their risks and will seek informed consent from all participants.

General procedures to minimize risk:

Mathematica has implemented policies, procedures and safeguards to maintain the confidentiality of data provided to us for this evaluation. The confidentiality of all data provided will be maintained. We train staff in security and privacy awareness as well as specific procedures and techniques for maintaining data confidentiality. Mathematica uses secure servers, a firewall, and computers that are password protected with full disk encryption. We may store some PID for focus group respondents, such as names, phone numbers, email addresses; any documents containing PID will be kept on secure drives and in restricted access folders that only those who

are working with the data will have access to. We will not connect PID to the data we collect during the focus groups, and we will not connect names to the information we include in our reports. There is a small risk that researchers could inadvertently share PID, for example, by accidentally sharing a file with respondent names and personal information. To reduce the chance of this happening, we provide guidance on this in our security training with procedures for preventing inadvertent sharing PID. In addition, Mathematica staff receive annual training on how to maintain and securely protect data and must certify that they received and passed the training session.

AUDIO/VIDEO RECORDING RISKS

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

We will audio record using the web-based meeting platform recording capabilities and DVR recorders. Audio recording could potentially increase the risk to subjects' confidentiality if the recordings were inadvertently lost or shared with others outside of the project team. The audio recorders are not encrypted. However, we will keep the devices physically secure by keeping them with the interviewer when in use. Upon completion of each focus group, we will transfer audio recordings from the web-based meeting platform and the DVRs to a folder on our secure password protected network with access restricted only to those given permission by our project director and then delete the audio recordings from the web-based meeting platform and DVR device. The audio recordings will be used to create transcripts of the focus groups, which will facilitate analysis of the data and summarize themes for our interim report.

To minimize risk of recordings and PID being inadvertently shared, we will use the following practices:

1. Upon completion of each focus group, we will immediately transfer audio recordings to our secure folder with restricted access to only those who are working with the data. We will then immediately erase the audio files from the web-based meeting platform and DVR recorders.
2. After receiving permission to do so from the respondent, we will only include in the audio recordings the first (not the last) names of the participants.
3. The audio filenames will not include participant names when stored on our secure server or when shared with the transcription service.
4. We will have the audio recordings transcribed by a transcription service and will use a secure file transfer site to deliver the electronic audio recordings of the focus groups for transcription. We will receive transcripts through secure transfer and save them to our secure password protected network drive folder with restricted access.
5. We will then remove all first names included in the transcripts and maintain the transcripts within the secure drive.
6. We will require the transcription service to delete the audio recordings and transcripts within 90 days of our receipt of the transcripts.

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.

Not applicable. No medical services will be provided to subjects in this study.

INTERNATIONAL RESEARCH

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

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

No

LESS RISKY METHODS

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

We consider the methods we are using for this study to be low risk. Creating audio recordings of our data collection could pose minimal risk (for example, if audio files were inadvertently lost or shared), but greatly enhances the quality of the data we are collecting. For example, through audio recordings, we will have complete transcripts of our focus groups, which will provide richer, more complete qualitative data than we would have if we instead only relied on our notetaking during the focus groups.

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.

Participants in the focus groups will benefit directly by receiving a \$50 VISA gift card incentive payment. Participants who begin the focus group but do not stay for the full session will receive a pro-rated portion of the \$50 incentive based on the amount of time they actively participated.

Participants might benefit indirectly from the opportunity to share their experience and inform improvements in the implementation of CYBHI, but otherwise would not experience direct benefit from participating. CalHHS will use the data to make decisions about CYBHI implementation. The data collected might also be used by the California legislature and could help shape legislation aimed at creating or improving similar types of programs in the future.

JUSTIFICATION OF RISKS

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

Risks to subjects are minimal. The collected data will help inform the implementation of CYBHI and the state of California to achieve its goal of improving the wellbeing of children, youth, and their caregivers.

Administrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

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

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

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

HIPAA IDENTIFIERS

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

Name

Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)

Telephone numbers

Email address

TRAINING PROCEDURES

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

All Mathematica employees take mandatory, annual security and privacy awareness training. All staff working on this evaluation project who will have access to PID will receive training annually on data security policies and procedures relevant to this evaluation project, and are required to sign a confidentiality pledge. A copy of the document used to deliver the training is available upon request, and signed confidentiality pledges are available, if requested, for all staff working on the project.

STAFF VETTING PROCEDURES

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

Mathematica conducts thorough reference checks on employees before hiring, including the veracity of statements on CV, level of education, certifications, and references to assure there is no indication that the worker may present a risk to the security or integrity of confidential data or a risk for theft or misuse of confidential data.

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.

2023-108_CLS_STR_data collection_IRB Support
Letter for Mathematica.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.

Data collected for the purpose of the California Youth and Behavioral Health Initiative Evaluation will only be used for the evaluation. Project-specific training includes direction to project staff to never share project data unless authorized to do so by the Mathematica project director. All data that includes PHI/PII and other sensitive information will be stored in a secure location with restricted access. Electronic data stored in these locations will be automatically encrypted at rest and will be destroyed at the end of the project. Data will be transmitted using secure, encrypted transmission procedures through either the DHCS secure transfer site or Mathematica's secure Box site, which is compliant with HIPAA, HITECH, and FedRAMP for security of PHI and PII. Upon termination or expiration of the project's contract, all confidential data received from DHCS (or created or received by Mathematica on behalf of DHCS) that Mathematica still maintains in any form shall be cleared, purged, or destroyed consistent with NIST Special Publication 800-88, Guidelines for Media Sanitization. We will send written certification of the destruction to DHCS and any other data providers that require it no later than 30 days after data destruction.

CONFIDENTIALITY OF PUBLISHED DATA

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

The evaluation will not result in published information that could possibly be used to identify an individual respondent or beneficiary.

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?

N/A

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.

Yes, access to the data will be limited only to staff involved in the evaluation work. The primary investigator must authorize access to secure directories containing all project data. Mathematica's IT storage team grants access as authorized by the project director.

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.

N/A

LINKAGES

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

No

DESTRUCTION OF PID VERIFICATION

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

Yes

DATA SECURITY LETTER

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

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

Signed_51719_Mathematica Data Security
Letter_CLS.pdf

Data Security
Letter

Physical Safeguards

DATA PROTECTION

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

Yes

DATA DESTRUCTION

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

Yes

RETAINED DATA

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

data will be de-identified

Explain what identifiers will be removed and how.

Each focus group will be assigned a unique de-identified study ID number. We will save audio recordings and transcriptions on our secure server and use filenames that use the study ID number. We will store the unique focus group ID numbers in a separate subfolder within the restricted access folder on Mathematica's secure server from the focus group recordings or transcriptions.

The audio recordings will be maintained as electronic copies and kept in a restricted folder on our secure password protected network drive. We will save audio recordings with filenames that include unique study ID numbers (and not participant names) when stored on our secure server or when shared with transcription service. During the focus groups, we will only use participants' first names so the recordings will not capture the last names of participants.

We will have the audio recordings transcribed a transcription service. We will use a secure file transfer site to deliver the electronic audio recordings of the focus groups for transcription. We will receive transcripts through secure transfer and save them to our secure folder with restricted access. We will then remove all first names included in the transcripts and maintain the scrubbed transcripts within the secure drive.

Our contract with CalHHS requires the destruction of data within 15 days of expiration or termination of the contract. Our contract is currently set to expire on June 30, 2026, so data will be destroyed by July 15, 2026.

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.

We do not anticipate collecting any confidential documents or PID from focus group participants. We will acquire consent verbally. We do not expect to receive PID in paper form for any administrative data from CalHHS or the implementing agencies, but if we do, we will dispose of it as with the consent forms by cross-cut shredding.

FAXING

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

We will not be using fax machines to contact potential study subjects. We will contact study subjects using email or telephone.

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.

We will not have mailings of PID.

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.

The focus group discussions will use electronic protocols without PID. Web-based meeting platform and DVR recordings sent to the transcription service may include first names. Once we receive transcripts from the transcription service, we will remove all first names included in the transcripts immediately after receipt and maintain scrubbed transcripts within the secure drive. DVR recordings will be immediately uploaded to a secure Mathematica location as well as web conferencing recordings. The focus group(s) on the DVR will be wiped as soon as upload is confirmed.

Protocols, focus group notes, recordings, and transcripts will be kept in restricted folders within a restricted drive on Mathematica's secure network behind a firewall.

Audio recordings of the focus groups will be delivered electronically to a secure storage site for transcription by the transcription service. We will keep all these electronic audio recordings in a restricted folder within Mathematica's restricted access drives on Mathematica's secure network behind a firewall. When the study ends, we will delete all audio recordings. Only staff with a need to know will have access to the folder on the restricted drive. The transcription service will be required to maintain similar security procedures. Once we receive the transcripts back from the transcription service, we will require that the transcription provider destroy all audio recordings along with any written transcription and send a written confirmation of destruction. Additionally, once we receive transcripts through secure transfer and save them to our secure folder with restricted access, we will remove all first names included in the transcripts and maintain them within the secure drive.

Confidential data will not be copied to other folders or media that can be accessed by others or portable media such as CDs or flash drives. We will not store any confidential data on laptops.

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.

All Mathematica's access-controlled offices are located in buildings which are also access-controlled 24 hours a day. Only authorized staff with Mathematica key cards can enter the buildings. Visitors must request entry with a buzzer or get a pass from building security before accessing a Mathematica office. Visitors must also sign a log-in sheet stating their name, date and purpose of their visit; and they will be escorted while on the premises.

SERVER SECURITY

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

Data stored on Mathematica servers are encrypted, and housed in locked server rooms within Mathematica's locked office suites. Only authorized information technology staff with key cards may access the server rooms.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Each focus group will be assigned a unique de-identified study ID number. We will save audio recordings and transcriptions on our secure server and use filenames that use the study ID number. We will store the unique focus group ID numbers in a separate subfolder within the restricted access folder on Mathematica's secure server from the focus group recordings or transcriptions.

The audio recordings will be maintained as electronic copies and kept in a restricted folder on our secure password protected network drive. We will save audio recordings with filenames that will include unique study ID numbers (and will not include participant names) when stored on our secure server or when shared with the transcription service. During the interviews, we will only use participants' first names so the recordings will not capture the last names of any participants.

We will have the audio recordings transcribed by a transcription service, such as Data Gain. We will use a secure file transfer site to deliver the electronic audio recordings of the interviews for transcription. We will receive transcripts through secure transfer and save them in our secure folder with restricted access. We will then remove all first names included in the transcripts and maintain the scrubbed transcripts within the secure drive.

DISK STORAGE

State whether all disks with PID will be destroyed.

We do not anticipate having any disks with PID. But if we do have any PID on disk, cassette, or flash drive, we will destroy it at study end according to consistent with NIST Special Publication 800-88, Guidelines for Media Sanitization.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All Mathematica workstations have FIPS 140-2 compliant full disk encryption. All staff computers have password protection. Passwords must be changed every 30 days.

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.

Staff are instructed never to store PID on workstations unless there is a business need, and the storage is approved by the project director. All Mathematica workstations have FIPS 140-2 compliant full disk encryption.

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.

Staff are instructed never to store PID on laptops unless there is a business need, and the storage is approved by the project director. All Mathematica workstations (including laptops) have FIPS 140-2 compliant full disk encryption.

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.

If PID on removable media is required, the storage must be approved by the project director and the file or media must be secured with FIPS 140-2 compliant encryption.

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.

Security patches are applied on all workstations, laptops, servers and storage appliances that house PID. Patches are applied during routine monthly maintenance, or on an emergency basis as needed. Operating systems and applications are kept current to the latest stable releases and updated with newly released security patches, service packs, and hot fixes as they are made available by the vendors.

PASSWORD CONTROLS

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

Strong passwords are required to access workstations, laptops, servers and removable media at Mathematica. Every Mathematica employee is required to have passphrases, a short sentence including punctuation and spaces to make the passphrases more difficult to guess/crack. The passphrase policy aligns with federal recommendations for contractors as well as with the most current and effective best practices for cybersecurity. The passphrase policy is as follows:

- Password change frequency: Does not expire
- The minimum password length: 15 characters
- Password history: Passphrase can be reused after 24 changes

Employees are asked not to write the passphrase down. Employees are asked not to tell passphrases to colleagues or friends. If an employee must share a passphrase (such as with a Mathematica computer technician), they are required to change their passphrase as soon as possible afterwards. Passphrases should be creative and are encouraged to use spaces. Employees are asked not to use their names, their kid's names, etc.

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.

Yes, sufficient system security controls are in place for automatic screen timeout (10 minutes), automated audit logging, host-based intrusion detection and prevention, anti-virus, and periodic system security/log reviews.

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.

All transmissions of electronic PID outside the secure internal network will be secured using FIPS 140-2 compliant encryption. Staff are instructed to only use project approved data transmission methods. PID may only be sent via email only if there is an emergency business need, and if it is in an encrypted (FIPS 140-2 validated encryption) attachment to the email (password shared via means other than email). Website and file transfer must use https:// and use Transport Layer Security higher than version 1.0, and only if the method requires a password and/or multifactor authentication.

INTERNET ACCESSIBILITY

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

No PID in electronic form will be accessible to the internet.

DISPOSING OF PID

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

Mathematica will dispose of electronic PID through secure wiping, or the native secure deletion features of our network storage appliance, consistent with NIST Special Publication 800-88, Guidelines for Media Sanitization.

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.

Once the respondent agrees to participate, we will coordinate a time for the virtual focus group. We will ask caregivers to provide their consent on the consent forms as well as their verbal consent before we begin recording the focus group. For minor participants, parents/guardians will be asked to complete the active consent form prior to the youth being assigned to a focus group. Youth will also provide verbal assent at the start of the focus group. We include the consent form in the attachment called "Consent Forms" and the assent language included in the youth protocol in the attachment called "CLS_Youth Listening Session Protocol."

The Mathematica team will send a calendar invitation via email that includes the date and time of the focus group, access information for the web-based meeting conferencing platform, and an attachment of the consent script as a PDF. The consent script includes an explanation of what participation involves, the risks and benefits, and that participation is voluntary and confidential, and the respondent can stop the session at any time and refuse to answer any of our questions.

We will also read elements of the consent script to participants at the start of the focus groups, including that participation is voluntary, that the participants confirm to a part of the study, that the participants may decline to answer any of our questions, that we will record the discussions with consent, and keep information confidential. We will also explain the risks and benefits associated with participating in the focus group.

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.

CLS_Youth Listening Session Protocol_submission.docx	Consent Form
Consent Forms_submission.docx	Consent Form

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 will be obtained from all youth participants ages 14–17 prior to their participation in focus groups. Upon receipt of a signed parental/legal guardian consent form, selected youth will be invited to join a scheduled focus group session. Youth will only be scheduled for a focus group session once the signed parental/legal guardian consent form has been received.

At the start of each session, the facilitator will provide a standardized verbal overview of the study, including the purpose of the research, what participation entails, potential risks and benefits, the voluntary nature of participation, and the participant's right to withdraw at any time without penalty.

After this information is presented, youth will be asked to provide verbal assent to indicate their understanding and willingness to participate. Facilitators will be trained to assess participants' comprehension and comfort level before obtaining assent. If a youth does not provide verbal assent, they will not participate in the session.

Documentation of verbal assent will be recorded by the facilitator on a secure tracking form, which will include the date, participant ID, and the initials of the staff member collecting the assent. This documentation will be securely stored and maintained in accordance with our data protection protocols.

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.

CLS_Youth Listening Session Protocol_submission.docx Assent Forms

HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

CYBHI_BudgetSummary_Task3.pdf Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

CYBHI_IRB_Mathematica_Cover Letter_CLS.pdf Cover Letter

In order for the PI to review and sign this form, you will need to click "Next" and on the next page, click "Submit." At that point the PI will receive notification that will need to review the application and if they request changes, they will return the form to you and you will receive an email notification.

PI Signature for Coordinator Submission (Initial)
- Submitted 05/02/2025 3:53 PM ET by Dan Friend, Ph.D

PI Review

Please click "Next" and "Submit" in order to submit this application, regardless of whether or not it is ready for review. If you indicated it is ready for review, it will go to the Responsible Official for review and signature, and if not, it will be returned to the individual who completed the form for changes.

Is this application ready to be reviewed by the IRB? If not, choose no to have the application sent back to the coordinator for revisions.

Yes

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

Signed Friday, May 2, 2025 3:53:10 PM ET by Dan Friend, Ph.D

Responsible Official Signature
- Submitted 05/02/2025 4:08 PM ET by Rick McManus, MPP

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 Friday, May 2, 2025 4:08:04 PM ET by Rick McManus, MPP

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 05/09/2025 1:59 PM 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

This is a research with human subjects' contacts. Researchers from Mathematica have submitted this study (Caregiver, Youth & Young Adult Focus Groups) which is part of the California Children and Youth Behavioral Health Initiative (CYBHI), funded by CalHHS under contract 2022-197-CYBHI and led by Mathematica. This study aims to evaluate CYBHI's impact by conducting 30 focus groups with youth, young adults, and caregivers across California to examine how communities have used CYBHI funding to address behavioral health disparities. Importantly, the study does not request or use any state data to identify or contact participants; instead, recruitment is conducted directly through CYBHI-funded community organizations. The findings will be summarized in the Community Spotlight Report, publicly available on the CYBHI website, and will inform policymakers about successes, gaps, and areas for improvement in behavioral health services.

Choose the CPHS Chair

Catherine Hess, PhD

Select the vice chair of the committee

Larry Dickey, MD, MPH, MSW

Assign to Cycle

June

Assign to cycle year
2025

Chair Review and Full Board Set-Up
- Submitted 05/12/2025 3:44 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2025-066

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

Researchers from Mathematica have submitted this study (Caregiver, Youth & Young Adult Focus Groups) which is part of the California Children and Youth Behavioral Health Initiative (CYBHI), funded by CalHHS under contract 2022-197-CYBHI and led by Mathematica. This study aims to evaluate CYBHI's impact by conducting 30 focus groups with youth, young adults, and caregivers across California to examine how communities have used CYBHI funding to address behavioral health disparities. Importantly, the study does not request or use any state data to identify or contact participants; instead, recruitment is conducted directly through CYBHI-funded community organizations. The findings will be summarized in the Community Spotlight Report, publicly available on the CYBHI website, and will inform policymakers about successes, gaps, and areas for improvement in behavioral health services.

Assign SME to study

Larry Dickey, MD, MPH, MSW

Enter the meeting date for this project

06/06/2025

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.

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