

## View xForm - Project Application v6

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

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**Data entry**

**Amendment Header**

## Amendment Submitter

August 2024 cycle

\_\_\_\_\_ Full Board Amendment \_\_\_\_\_

07/09/2024 • Nicholas Zadrozna • Internal

This amendment should be discussed in the August 2nd, 2024, CPHS full board meeting.

07/14/2024 • Sussan Atifeh • Internal

Summary of the amendment:

- Focus: addition of a new Co-PI, and early data collection and analyses through qualitative key informant interviews (KIIs) with state-level policymakers, CalHHS agency staff, and child-serving organization staff.

- Updated Discussion Guide: Revision of the State KII discussion guide to capture perceptions of CYBHI implementation and effects within the past 12 months. Introduction of a sustainability section to gather perspectives on sustaining the initiative.

- Data Collection Details: Up to 50 virtual interviews (WebEx or Zoom) with state-level respondents, including policymakers, CalHHS staff, state education leaders, and child-serving agency representatives.  
Participants: State policy makers, CalHHS staff, state-level education leaders, child-serving agency leaders, and managed care plan representatives.

- Data Analysis: Descriptive and thematic analyses of interview data.

- Reporting: Findings will be reported to CalHHS and may be included in public-facing briefs and reports.

- Future Plans: Third Round of Interviews, planned for fall 2025, with amendments to be submitted for updated discussion guides.

•County-Level Data Collection: Subsequent qualitative data collection with county-level agencies planned for spring 2025, with future amendments for protocols and interview guides.

•Recruitment and Consent:

•Key Informants: Identification of key informants through known contacts, purposive snowball sampling, and website searches.

Outreach: Initial recruitment via email and telephone, followed by scheduling and confirmation of virtual interviews.

Consent Process: Verbal consent obtained before interviews, with detailed consent information provided in emails and during the interview setup.

•Goals and Objectives:

—Obtain information on CYBHI implementation context, barriers, facilitators, and sustainability factors.

—Use insights to identify elements of CYBHI that are working well and areas for improvement.

07/15/2024 • Sussan Atifeh • Internal

Dear Researchers: Please check all pages of the application (scroll down to see the entire page), address the comment(s), and resubmit the application by 12:00 pm on 7/16/2024.

Thanks,

07/15/2024 • Sussan Atifeh • *Not* Internal

Dana M Petersen, MA, MPH, PhD

**Email:** dpetersen@mathematica-  
mpr.com

**Business:** (510) 830-3703

**Instructions for amending your approved application:**

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

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

**PI:**

Joseph Zickafoose, MD, MS

**Email:** jzickafoose@mathematica-  
mpr.com **Business:** (734) 794-1123

**Administrative Contacts:**

**Name**

**Role**

**Protocol Number:**

2023-108

**Protocol Title:**

Evaluation of the Children and Youth Behavioral Health Initiative (CYBHI): Qualitative Data Collection and Analyses of Publicly Available, Deidentified Secondary Data

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

Addition and/or removal of project personnel  
Data collection

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

Researchers, please address in this section changing the title from "Evaluation of the Children and Youth Behavioral Health Initiative (CYBHI): Qualitative Data Collection and Analyses of Publicly Available, Deidentified Secondary Data" to "Evaluation of the Children and Youth Behavioral Health Initiative (CYBHI): Qualitative Data Collection Round 2".

07/09/2024 • Nicholas Zadrozna • *Not Internal*

This amendment adds new co-Principal investigator and updates to the State KII discussion guide.

We have reframed discussion guide questions to capture perceptions of the implementation and effect of the CYBHI within the past 12 months. These interview rounds occur about one-year apart. The interviews are intended to build a story over time.

We have also introduced a sustainability section. As implementation is underway, we are gathering perspectives on what elements of the initiative to sustain and the factors that influence sustainability. Findings from this section may offer insights on action to take to ensure successful sustainability of the initiative.

**We have decided not to change the title of the study. We will leave the title of the study as it was when we submitted the original application.**

**Indicate the Level of Risk involved with the changes proposed.**

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

Level of Risk has not changed

**PI City Output** *(Internal)*

Princeton

**PI Location State Output** *(Internal)*

New Jersey

**Personnel Information for Amendment**

**Please complete the questions below.**

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

New Contact Form

### Existing Personnel

Name	Role
Amanda Lechner, MPP	Co-Principal Investigator
Annu van Bodegom	Coordinator
Cara Orfield, MPP	Co-Principal Investigator
Dana M Petersen, MA, MPH, PhD	Co-Principal Investigator
Elisa Gonzalez, Ph.D	Research Team
Gina Sgro, MPH	Co-Principal Investigator
Holly Matulewicz, MA	Research Team
Joseph Zickafoose, MD, MS	Principal Investigator
Kate D'Anello, MPA	Responsible Official
Matthew Niedzwiecki, PhD	Co-Principal Investigator

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

Addition of Co-Principal Investigators

### Please click 'Add Contact' and add the email address of any new co-principal investigators

Jasmine Little, MA

**Email:** JLittle@mathematica-mpr.com

**Business:** (609) 945-6585

### Additional document is required, please upload CVs.

Jasmine Little\_CV.docx Co-PI Curriculum Vitae

## Project Information

### SUBMITTER

#### Application completed by:

Dana M Petersen, MA, MPH, PhD

**Email:** dpetersen@mathematica-  
mpr.com

**Business:** (510) 830-3703

### PREVIOUSLY APPROVED EXEMPTION

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

No

### PROJECT TITLE

Is it necessary to change the project's title?

07/14/2024 • Sussan Atifeh • *Not Internal* • Resolved

changes in project's title would not be reflected in the main page of the application automatically and if necessary should be done manually.

07/14/2024 • Sussan Atifeh • *Not Internal* • Resolved

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

Not necessary to change the title. We can keep the title the same for the remainder of the evaluation. Thankyou.

Evaluation of the Children and Youth Behavioral Health Initiative (CYBHI):  
Qualitative Data Collection and Analyses of Publicly Available, Deidentified  
Secondary Data

## STUDY PROCEDURES

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

You have de-selected "Recruitment-Participant" and "Survey" in this section. Please re-select them if you should continue to recruit participants and surveying them as components of previously approved amendments or initial submission of this project.

In other words, are you still doing any activities regarding "Recruitment-Participant" and "Survey" which were approved in previous submissions? If yes, then re-select these two options.

Please note since you decided to submit subsequent requests as "amendments" for the original project 2023-123 (instead of submitting them as new project application), you should keep all components previously approved for this study (via previous submissions) unless you are not doing that specific activity anymore. For example, if you don't survey participants any more, then you can de-select it.

07/14/2024 • Sussan Atifeh • *Not* Internal • Resolved

Interviews  
Program Evaluations  
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.

You have added HIPAA waiver to the previously selected options (approved in previous submissions). Are you requesting a HIPAA waiver from CPHS? If no, please de-select the "HIPAA Waiver" option in this section.

07/15/2024 • Sussan Atifeh • Not Internal • Resolved

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

Minimal Risk  
Consent 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.*

Not applicable

## **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.**

This amendment should be discussed in the August 2nd, 2024 meeting and is not qualify for an expedited review. Please select "Not applicable."

07/15/2024 • Sussan Atifeh • Not Internal • Resolved

*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.**

Researchers: Please change the date to 08/15/2023 since that was the date on the initial submission for this protocol (this date should not change in amendments)

07/09/2024 • Nicholas Zadrozna • *Not Internal* • Resolved

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

08/15/2023

**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.**

July 5, 2024 Amendment:

This application focuses on data collection and analyses that pose low risk to study participants: qualitative key informant interviews with state-level policymakers, state-level CalHHS agency staff and other child-serving organization staff.

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. In 2022, CYBHI was integrated as the core of Governor Gavin Newsom's Master Plan for Kids' Mental Health. 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—from prevention to treatment to recovery—for all children and youth ages 25 and younger, regardless of payer.

The California Health and Human Services Agency (CalHHS) has funded a multi-year mixed-methods evaluation of CYBHI's progress toward its overall goals. The evaluation seeks to inform future decisions by policymakers based on what the CYBHI accomplished and what was learned in the process of implementation. Three fundamental research questions guide this evaluation: (1) How is CYBHI implemented?, (2) For whom, how, and in what context did CYBHI progress toward achieving its intended transformation?, and (3) Did the initiative progress towards improving population behavioral health outcomes?

In this second amendment to the original application we are conducting quantitative and qualitative data collection in nine California counties. This will include a Network and Ecosystem Experiences survey (NEES) and key informant interviews with representatives of child- and youth-serving agencies and organizations to better understand county behavioral health policy, the implementation of CYBHI-funded workstreams, multisector collaboration, and how the behavioral health ecosystem changes over time. The network survey and interview data collection activities complement each other to provide more holistic answers to our research questions. The county data collection and analyses described in this amendment will be summarized in internal reports to CalHHS, publicly available reports on the

CYBHI website ( <https://cybhi.chhs.ca.gov/>), and potentially peer-reviewed publications.

## **MAJOR RESEARCH QUESTION**

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

The data collection described in this IRB application will provide a foundation for addressing these major research questions over the course of the CYBHI evaluation:

#### Policy questions:

- How has the policy environment influenced the implementation and outcomes of the CYBHI initiative?
- How has CYBHI influenced policy changes or modifications to other programs?
- How can CYBHI-related policy be improved to promote equitable youth behavioral health and well being?

#### Systems change questions:

- How has CYBHI changed the systems of care involved in promoting youth behavioral health and well-being?
- How has CYBHI addressed and improved equity within the systems involved in promoting youth behavioral health and well-being?

#### Implementation questions:

- How has the CYBHI been implemented and what were the key processes involved?
- How has implementation of the CYBHI addressed and improved equity in promoting youth behavioral health and well-being?

#### Outcomes questions:

- Is CYBHI associated with improved youth behavioral health and well-being outcomes?
- Is CYBHI associated with improved equity in youth behavioral health and well-being outcomes?

The survey and interview data collection we describe in this amendment will help to answer the study-wide research questions related to policy, systems change, and implementation as defined in the original IRB application at the county level (project number 2023-108 with approval received 8/16/23). Nuanced aspects of these questions specifically addressed by these new study components include:

1. Policy: How do counties leverage policy efforts in combination with CYBHI to address the behavioral health needs of children, youth, and families?
2. Systems: What is the baseline behavioral health ecosystem within counties, and how does it change during CYBHI implementation? What factors influence collaboration and integration across the county behavioral health ecosystem?
3. Implementation: How is CYBHI implemented within a county? What are the facilitators and barriers to implementation?

## 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**

internal note- new consent forms, interview guides, and outreach information attached to this section of the application

07/09/2024 • Nicholas Zadrozna • Internal

Please update the phone number for contacting CPHS at the end of the interview consent script.

07/20/2024 • John Schaeuble, PhD, MS • *Not* Internal

A one-page FAQ document is mentioned at several places in your materials but is missing here. Please provide it or remove the references mentioning it.

07/20/2024 • John Schaeuble, PhD, MS • *Not* Internal

July 5, 2024 - Amendment

Qualitative data collection

We will conduct initial primary qualitative data collection through key informant interviews. In fall 2024, we will conduct up to 50 interviews with a variety of state-level respondents. Respondent types include state policy makers (e.g., committee staffers and legislative staffers); CalHHS staff directly involved in CYBHI implementation, data collection or monitoring; state-level education leaders (e.g., State Board of Education and California Department of Education, state association of county superintendents of offices of education, state association of school psychologists); state-level leaders at child-serving agencies (e.g., CalHHS departments such as Health Care Services (including mental health and CalAIM), Public Health, and Social Services (including foster care and child welfare); CA Division of Juvenile Justice; statewide organizations such as the California Alliance of Child and Family Services), and state-level managed care plan representatives. Through these interviews, we will continue to learn about CYBHI early implementation context and emerging barriers and facilitators to implementation. We include the master key informant discussion guide in the attachment call "State\_KII Protocols\_Discussion Guide\_Round 2\_IRB."

All interviews will take place virtually, using a web-based platform (WebEx or Zoom) with video or audio-only, depending on each respondent's preference. We will plan to record all key informant interviews so that we can submit



recordings for transcription by a transcription service. This will ensure complete and accurate data. We will include written language about recording the interviews in the consent script. The consent form is included in the attachments called "State\_KII Protocols\_Interview Consent Form\_Round 2." We will destroy all recordings at the end of the study.

The primary data we collect will be analyzed using common qualitative methods such as descriptive and thematic analyses, and we will produce a report for CalHHS. We plan to repeat state-level qualitative data collection for a third round in the fall of 2025, and we will submit amendments to this application with updated discussion guides to reflect the evolution of the initiative and the evaluation. This second round of state-level interviews is informed by the first round of interviews, and will inform subsequent qualitative data collection with county-level agencies and organizations serving children and youth in spring 2025. We will submit an amendment to this application when protocols and interview guides for that data collection are prepared.

For this amendment and second round of state KII data collection, we do not have any change to the introduction and consent script or the recruitment email outreach materials. We will continue to use the content that worked well in the first round.

#### Previous Amendment:

We will conduct the web-based Network and Ecosystem Experiences Survey (NEES) and virtual (via WebEx) key informant interviews in nine California counties: Alameda, Fresno, Humboldt, Imperial, Lake, Los Angeles, Monterey, Placer, and Ventura . We purposively selected the counties in conjunction with CalHHS based on several factors, including the Mental Health Services Act region, the implementation of CYBHI-funded workstreams, participation in the Transforming Together Demonstration Project (coordinated implementation of CYBHI and Community Schools Partnership Program), population density; the California Healthy Places index, and resident demographic characteristics.

We will review internal documents, conduct internet research, and work with CalHHS and local partners to identify potential respondents to each data collection. We acknowledge that conducting a web-based survey and virtual interview may present a barrier to some participants who may lack internet access. We intend to use these data collection modes because they offer substantial benefits that outweigh this limitation, including ease of reach and convince for participants. We will administer the survey first and follow with the interviews approximately one month later. We will recruit potential respondents for each data collection activity using a multi-stage email recruitment approach, consisting of an initial email and 3 reminder emails sent approximately 1 week apart. We may also reach out via telephone if an email address is unavailable. Potential respondents for each data collection activity will include adult administrators of child- and youth-serving agencies and organizations that support children and youth behavioral health. This

will include representatives of county government agencies (e.g., behavioral health, child welfare, juvenile justice, education, public health, First 5, Regional Centers), managed care organizations, and community-based organizations. If the intended survey and interview respondent is the same person for an individual organization, we will let the individual know during survey recruitment that we will also be reaching out to request they participate in a follow-up interview in approximately one month, which they can opt out of doing if they choose. We will also include language in the interview recruitment emails for these individuals to let them know we understand that they already completed a survey and explain how the interview topics differ from, and build on, those in the survey. We will also give respondents who completed the survey the opportunity to opt out, or to ask someone else in their organization to participate in the interview on their behalf if they so choose.

We will not offer incentives to either the survey or the interview respondents. Some respondents receive CYBHI grant funding and may consider completing the survey or interview as part of the evaluation activities associated with their grant, but we acknowledge that this does not apply all respondents. Other respondents are county governmental officials and thus can not accept incentives.

To assess change in responses over time, we will conduct two rounds of survey and interview data collection in each county approximately 18 months apart. The first round will occur in the spring/summer of 2024, followed by a second round in fall of 2025. This spacing will allow our team to assess changes in workstream implementation and the behavioral health ecosystem over time without placing undue burden on county-level respondents. Across both rounds, we will aim to recruit the same organizations and individuals for the survey and interviews, although we acknowledge that staff turnover over 18 months may result in us surveying and/or interviewing different individuals within the same organizations. We will synthesize findings from the survey and interviews in county-level reports to CalHHS and the participating organizations, as well as cross-cutting and special topics reports if desired by CalHHS.

#### Network and Ecosystem Experiences Survey (NEES):

The survey is designed as a self-administered web-based instrument.

Upon receipt of IRB approval, we will field the survey over a 4-week field period. We will recruit one sample member to respond on behalf of each selected organization or department, conducting outreach via email. Sample members will click on a customized link provided in the recruitment emails to access and complete the survey on a computer or mobile device. The link will be tailored to the individual's email address and will not be accessible to others. The survey instrument will be tailored to each county's context (e.g., the relevant entities and multisector collaboratives present in a county). We will conduct testing prior to administration to ensure time required to complete is no more than 30 minutes.

Respondents will view a consent screen describing the purpose, length, and voluntary nature of the survey and must click that they "agree" before moving on to complete the survey. Links to the survey instrument and consent documents are below (See Network and Ecosystem Experiences survey and Network and Ecosystem Experience Survey Informed Consent Language attachments, respectively).

The survey instrument includes questions that ask respondents to report on

their organization's working relationships with other child- and youth-serving organizations in their county, as well as their organization's experiences participating in up to two multisector collaboratives. Respondents whose organizations do not participate in a multisector collaborative will answer questions about readiness to establish a multisector collaborative, after which the survey will terminate. The survey will be administered in English. We expect all survey respondents will speak and read English given their organizational positions.

The number of agencies and organizations recruited for the survey will vary based on the number of relevant agencies and organizations in each county, but we anticipate recruiting 15-20 organizations per county.

Key informant interviews:

The county key Informant interviews will use a standardized interview protocol tailored to each respondent's county and organizational context, such as the organization type (e.g., behavioral health, education, child welfare, managed care plans, juvenile justice, early childhood, public health, and community-based agencies or organizations that support the behavioral health of children, youth and families) and amount of funding received to implement CYBHI workstreams. The core topics of the interviews will be consistent across all counties, focusing on capturing a comprehensive view of each county's policy, programmatic, and systems landscape. Our county interview guide is included in the attachments called Key Informant Interview Protocol.

All interviews will take place virtually, using a web-based platform (WebEx) that can be accessed through the internet or by using a telephone to dial in to a toll-free number, and could use video or audio-only, depending on each respondent's preference. We will plan to record all key informant interviews so that we can submit recordings for transcription by a transcription service. This will ensure complete and accurate data. We will include written language asking for permission to record the interviews in the consent script.

We will attach a copy of the consent script as a PDF to the email and calendar invitations prior to the interview. We will read the consent content before initiating interview. If a respondent does not consent, we will terminate the interview (See document named Key Informant Interview Informed Consent Language for interview consent).

The number of agencies and organizations recruited for the interviews will vary based on the number of relevant agencies and organizations in each county, but we anticipate recruiting 12-16 organizations per county.

We will code the transcripts using the qualitative software package, NVivo, conducting descriptive and thematic analyses from the output. NVivo will be used within the Mathematica network.

**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.**

County Key Informant Interview Protocol Introduction and Consent Form  
Consent Script.docx

Network and Ecosystem Experiences Survey Consent.docx	Consent Form
County Key Informant Interview Discussion Guide.docx	Instruments
Network and Ecosystem Experiences Survey Instrument.docx	Instruments
State KII Protocol_Discussion Guide_Round 2_IRB.docx	Instruments
County Key Informant Interview Recruitment_Email Outreach.docx	Other Documents
Network and Ecosystem Experiences Survey Recruitment Email Outreach.docx	Other Documents
State KII Recruitment_Email Outreach_Round 2.docx	Other Documents
State KII Recruitment_Interview Consent Form_Round 2.docx	Other Documents

## RECORDING

### Will audio or video recording occur?

The consent script doesn't say anything about asking permission to use first name or allowing use of a pseudonym in the interview, which it should. You did explain this in your previously approved consent script. Please continue to use all previously approved text that is still relevant.

07/20/2024 • John Schaeuble, PhD, MS • *Not Internal*

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.).**

July 5, 2024 - State KII Round 2 amendment

We will record all interviews using the web-based meeting platform WebEx and digital voice recorders (DVRs) as backup. The DVR recorders are not encrypted. However, we will keep the DVR devices physically secure by keeping them with the interviewer. Upon completion of each interview, we will immediately download WebEx audio files from the WebEx application and upload DVR audio recordings to our secure, password protected network drive. This folder can only be accessed by staff authorized by the project director who are working with the data. We will then immediately erase the audio files from the WebEx application and the DVR recorders.

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 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 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—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 the 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.

We will erase the audio recordings from the WebEx application and the DVR recorders as soon as possible after completing each interview 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**

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## 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.**

July 5, 2024 - State KII Round 2 amendment:

### Qualitative data collection

In the fall of 2024, we will conduct up to 50 key informant interviews with a variety of state-level respondents. We will interview approximately state policy makers (e.g., committee staffers and legislative staffers); CalHHS staff members directly involved in CYBHI implementation, data collection or monitoring; state-level education leaders (e.g., State Board of Education and California Department of Education, state association of county superintendents of offices of education, state association of school psychologists); state -level leaders at child-serving agencies (e.g., CalHHS departments such as Health Care Services (including mental health and CalAIM), Public Health, and Social Services (including foster care and child welfare); CA Division of Juvenile Justice; statewide organizations such as the California Alliance of Child and Family Services); and state-level managed care plan representatives.

Interviewees for the key informant interviews will be selected based on their specific state-level roles and the perspectives they bring from those specific roles, rather than on any demographic or other characteristics. We plan to recruit participants based on sectors within the behavioral health ecosystem (for example, policy, CalHHS staff, education, and child-serving organizations). We expect all respondents in these groups will speak and read English. We expect each interview will last no more than 60 minutes.

### Previous amendment

The study population for the survey and interviews includes adult representatives of child- and youth-serving organizations aged 18 years and older. Desired agencies and organizations will include government (e.g., behavioral health, education, child welfare, juvenile justice, public health, early childhood), managed care, and non-profit entities across sectors that support children and youth behavioral health. The number of respondents to each data collection will vary based on the number of relevant agencies and organizations in each county.

We anticipate the survey sample will include approximately 15-20 organizations per county (sample size of 190 total possible respondents). We



anticipate the interview sample will include approximately 12-16 respondents per county (sample size of 144 total possible respondents). We expect all survey and interview respondents will speak and read English given their organizational positions. We expect that the survey will take up to 30 minutes to complete and that each key informant interview will last no more than 60 minutes.

For the survey, we will aim to recruit organizational representatives who are knowledgeable about their organization's participation in multisector collaborations for children and youth behavioral health. For the interviews, we will aim to recruit organizational administrators who are knowledgeable about policy, CYBHI-funded workstream implementation, and multisector collaboration.

Given the complementary nature of the topics covered in the survey and interviews, it is possible that we may recruit the same person to complete the survey and participate in an interview. However, we will work with our local partners to minimize overlap in our respondent lists where possible. Prior to beginning recruitment, we will crosswalk the survey and interview respondent lists to determine if there is overlap. If a respondent appears on both lists, we will advise them in the initial survey email invitation that we will reach out after the survey to request they participate in a follow-up interview in approximately one month, which they can opt out of doing if they choose. We will also include language in the interview recruitment emails for these individuals to let them know we understand that they already completed a survey and explain how the interview topics differ from, and build on, those in the survey. We will also give respondents who completed the survey the opportunity to opt out, or to ask someone else in their organization to participate in the interview on their behalf if they so choose.



## **RATIONALE**

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

July 5, 2024 - State KII Round 2 amendment:

The goal of the qualitative key informant interviews is to obtain exploratory, formative, and descriptive information about the various respondents' direct and indirect experiences with CYBHI and its implementation. To begin to address the major research questions, the focus of these interviews will be to learn about CYBHI early policy and implementation context, emerging barriers and facilitators to implementation, and perceptions of how the system of care and supports for children and youth's behavioral health is changing. The respondents can offer insight and opinions to help us to identify elements of CYBHI that are working well, and not well, and the types of actions that might improve the initiative in the future. The study team will summarize the interviews in reports to CalHHS and potentially in public facing briefs and reports.

#### Network and Ecosystem Experiences survey

The Ecosystem Working Paper describes the various sectors that must come together to reimagine and redesign the behavioral health ecosystem in California – a key goal of the CYBHI initiative. The goals of the NEES are to understand the relationships between county-level child- and youth-serving agencies and organizations across these sectors—behavioral health, education, juvenile justice, child welfare, health care, education, early childhood, public health, and community-based organizations—as well as whether these entities are collaborating to create greater alignment and integration across the ecosystem and about progress made towards that end. These sectors need to be involved to ensure integrated, equitable, accessible, and community responsive supports to improve behavioral health outcomes for children, youth, and families. To best understand the connections across sectors and multisector collaboration, we will aim to recruit administrators (adults aged 18 years and older) who are knowledgeable about their organizations' participation in multisector collaboration/collaboratives to complete the survey for their organization or department. We anticipate that these individuals will include administrators, such as directors, managers, and department leads; however, respondents may gather input from others in their organizations to help complete the survey. The respondents can offer important insights to help us understand the nuances of collaboration at a county level and what is helping and hindering progress toward an strong behavioral health ecosystem.

#### Key informant interviews

The county key informant interviews are designed to capture detailed

accounts of each county's experience in implementing CYBHI-funded workstreams and other behavioral health initiatives and to address policy, program, and systems evaluation questions. We will use a standardized interview protocol that will be tailored to each county's specific context based on ongoing CYBHI efforts and the sector of each specific respondent (e.g., behavioral health, education, child welfare, managed care plans, juvenile justice, early childhood, public health, and community-based agencies or organizations that support the behavioral health of children, youth and families). The core topics of the interviews will be consistent across all counties, focusing on capturing a comprehensive view of each county's policy, programmatic, and systems landscape. Given their specific and in some instances very niche roles, the respondents can offer insight and opinions to help us to identify elements of CYBHI that are working well, and not well, and the types of actions that might improve the initiative in the future.

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## 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.*

July 5, 2024 - State KII Round 2 amendment:

While awaiting IRB approval, we will begin identifying key informants from each of the desired sectors at the state level: policymakers, CalHHS staff, education leaders, representatives from child-serving agencies, and representatives from managed care plans.

We will use known personal contacts, as well as purposive snowball sampling strategies to identify key informants. First, we will identify respondents from our first round of State KII interviews whom we would like to speak with again. Second, we will assess gaps in our sample, and reach out to individuals already engaged in CYBHI who represent various sectors and are participating in or have participated in CYBHI activities, such as the cross-department CYBHI meeting workgroup, state-level mapping exercises, or the CYBHI Evaluation Advisory Group, to fill identified gaps. We will ask these individuals to agree to participate as key informants themselves or recommend other staff in their organizations to whom we should reach out to. Finally, we will identify respondents by searching websites to locate individuals holding director or manager titles at organizations, agencies, associations, or cross-sector working groups that represent state-level perspectives in each of the desired sectors and who have a role in the behavioral health system for children and youth.

After identifying our sample of respondents, we will attempt to secure introductions to new respondents from the California CYBHI Director and other initiative and state contacts. Regardless of whether we can secure a warm hand off, we will initiate recruitment by sending an outreach email explaining the evaluation and what participation involves (a one hour voluntary and confidential virtual video or audio call to learn about the respondents' experiences with and opinions about CYBHI, its progress, challenges, and success). We will contact those potential respondents for whom we do not have an email address (or if they do not respond to the email) by telephone to explain the study and request their participation.

Once the respondent agrees to participate, we will coordinate a time for the virtual interview. The interview team will send a calendar invitation via email that includes the date and time of the interview, web-based meeting platform access information, 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 interview at any time and refuse to answer any of our questions. We will send a reminder email 1 day before the interview is scheduled to take place, re-sharing the details of the interview (date, time, WebEx access information, consent script).

We will request verbal consent from respondents over the phone before we begin the interview.

The recruitment materials for the key informant interviews, including our outreach and follow up emails and confirmation email, are in the attachment called, "State\_KII Recruitment Email\_Outreach\_Round 2"

#### Previous Amendment:

##### Overall recruitment processes

While awaiting IRB approval, we will begin identifying potential respondents for the survey and the interviews in preparation for contact after receiving approval. We will use similar, though varying processes, to identify the respondents best suited to each data collection effort. General processes include reviewing internal documents, conducting internet research, and working with known contacts at CalHHS and local partners. Across the survey and interview data collection, we hope to identify respondents from desired organizations including government-funded agencies (e.g., behavioral health, child welfare, juvenile justice, public health, early childhood (e.g., First 5, Regional Centers), and community-based organizations.

Below, we describe the specific processes we will use to identify survey respondents and interview respondents, in turn. Note that prior to initiating recruitment, we will crosswalk the survey and key informant interview respondent lists to identify overlap. If we have identified the same individual at an organization to recruit for the survey and interviews, we will include language in the initial survey recruitment emails to notify the respondent that we will reach out to after the survey to request they participate in a follow-up interview in approximately one month, which they can opt out of doing if they choose. We will also include language in the interview recruitment emails for these individuals to let them know we understand that they already completed a survey and that they can opt out, or invite someone else from their organization to participate in the interview on their behalf if they so choose.

##### Network and Ecosystem Experiences survey

We will review internal documents, conduct internet research, and work with CalHHS and local partners to identify relevant child- and youth-serving agencies and organizations for the survey. CalHHS and partners knowledgeable about multisector collaboration in the selected counties will

assist in identifying individuals who can report on their organization's participation in multisector collaboration to lead survey completion for their organization.

After identifying the list of potential survey respondents in each county, we will use a multistage email recruitment approach, consisting of an initial email and 3 reminder emails. There will be one reminder email sent each week starting from the second week of survey administration. The emails will explain the purpose and length of the survey, information on the benefits of participation (e.g., receive a summary of findings for local use), and contain a link to access the web-based survey. We will send the emails approximately one week apart. Potential respondents will view a consent screen and must agree to participate prior to beginning the survey. The consent screen includes an overview of the purpose, risks and benefits, and voluntary and confidential nature of the survey.

The recruitment materials for the survey, including initial and follow-up emails are in the attachment called, Network and Ecosystem Experiences Survey Recruitment Email Outreach.

#### Key informant interviews

We will begin identifying potential respondents by reviewing internal documents to identify organizations in each county that received funding through CYBHI; however, the interviews will not be limited to these organizations. We also will search the websites of desired organizations to identify individuals holding specific roles, such as directors and deputy directors. We also will work with CalHHS and local partners to identify and fill gaps in our proposed sample. Finally, we will ask recruited individuals to agree to participate as key informants themselves or recommend other staff in their organizations to whom we should reach out. We will contact those potential respondents for whom we do not have an email address (or if they do not respond to the email) by telephone to explain the study and request their participation.

Once the respondent agrees to participate, we will coordinate a time for the virtual interview. The interview team will send a calendar invitation via email that includes the date and time of the interview, WebEx access information, 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 explains that the respondent can stop the interview at any time and refuse to answer any of our questions. We will send a reminder email 1 day before the interview is scheduled to take place, re-sharing the details of the interview (date, time, WebEx access information, consent script). We will request verbal consent from respondents over the phone before we begin the interview.

The recruitment materials for the key informant interviews, including our outreach and follow up emails and confirmation email, are in the attachment called, Key Informant Interview Recruitment Email Outreach.

**Attach copies of all recruitment materials.**

County Key Informant Interview Recruitment_Email Outreach.docx	Recruitment Materials
Network and Ecosystem Experiences Survey Recruitment Email Outreach.docx	Recruitment Materials
State KII Recruitment_Email Outreach_Round 2.docx	Recruitment Materials
State KII Recruitment_Interview Consent Form_Round 2.docx	Recruitment Materials

**SCREENING**

**Will subjects be screened prior to entry into the research?**

No

**COMPENSATION**

**Will subjects be compensated for participating in the study?**

No

## 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.*

July 5, 2024 - State KII Round 2 amendment:

This IRB application covers qualitative data collection between fall 2024 and winter 2025.

Qualitative data collection. Key informant interview respondents will participate in interviews one time and each interview will last approximately 60 minutes. Total approximate time commitment for interviewees is one hour. We anticipate repeating these interviews the following year with many of the same interviewees, but anticipate there will be new interviewees due to turnover in positions and to gain additional perspectives.

### Network and Ecosystem Experiences survey

We will administer the network and ecosystem experiences survey twice approximately 18 months apart in spring/summer of 2024 and the fall of 2025. We estimate that the survey will take up to 30 minutes to complete during each round. We anticipate recruiting the same organizations and respondents to complete the survey during both rounds; however, this may vary slightly if we identify new organizations to survey and/or if there is turnover in positions within the organizations surveyed in the first round.

### Key informant interviews

We will conduct key informant interviews twice approximately 18 months apart in spring/summer of 2024 and the fall of 2025. We anticipate the first round of interviews to run from May 2024 through July 2024 and the second round to run from November 2025 through January 2026.

County key informant interview respondents will participate in interviews one time per round of data collection. Each interview will last up to 60 minutes. There may be overlap between key informants during the first and second round of key informant interviews, although we anticipate some new respondents due to turnover in positions and to gain additional perspectives.

## 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.**

July 5, 2024 - State KII Round 2 amendment

Risk level is minimal. The main risk to key informant interview respondent participants is of inadvertent loss of confidentiality. Mathematica's standard security procedures minimizes this risk. The data we are collecting from key informant respondents is about their involvement, perceptions, and opinions of CYBHI and is not personal or sensitive. We will maintain the confidentiality of respondents' specific interview responses, but given the roles of some state-wide key informants, we will make it clear that their participation in the study itself will not be confidential. Participation is voluntary. Interview respondents may choose to not answer any or all questions or stop the interview at any point. 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 study. The confidentiality of all data provided will be maintained. We train staff on 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 key interview 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 in interviews, 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 of 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.

Previous amendment:

Risk level is minimal. There are no sensitive questions asked as part of the NEES or the county key informant interviews. The main risk to survey and



interview respondent participants, is of inadvertent loss of confidentiality of their responses. Mathematica's standard security procedures minimizes 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. Below, we describe possible risks to participants in the survey and interviews, in turn.

#### Network and Ecosystem Experiences Survey

The NEES is an organizational-level survey; we will not link the names of individuals completing the survey for their organizations to results in any of our reports. The data collected are not personal or sensitive. To illustrate connections across the behavioral health ecosystem in each county, we will report the relationships between organizations (results of questions B2-BX on page 7 of the survey), in a network map. The maps will depict each organization as a node and label the organization sector (e.g., behavioral health, education, community-based organization). Lines between nodes will depict the type of connection (cooperate, coordinate, collaborate, integrated) reported by each organization with each other organization. The maps will not include lines if a connection is not reported. We will not report the organization or department name in the maps to minimize the risk of loss of confidentiality. Answers to the questions about multisector collaboratives will be reported as frequencies; we will not identify organization types or report the data if fewer than three organizations report on a particular collaborative. See questions B2-BX on page 7 of the survey instrument in the document named: Network and Ecosystem Experiences Survey

#### Key informant interviews

The data we are collecting from key informant respondents is about their involvement, perceptions, and opinions of CYBHI and/or other initiatives and is not personal or sensitive. We will maintain the confidentiality of respondents' specific interview responses, but we will make it clear that in some cases it may be difficult to maintain the confidentiality of participation in the study itself. That is, given the small number of behavioral health-related organizations in a county and the role of a respondent, a reader of a publicly available report may be able to discern the respondent's name. . Participation is voluntary. Interview respondents may choose to not answer any of all questions or stop the interview at any point. 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 study. The confidentiality of all data provided will be maintained. We train staff on 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. The programs that will be used for survey data collection is QuestionPro, and the key informant interviews is Cisco WebEx. Both

programs are secure online platforms. QuestionPro is a web-based survey data collection software that is hosted in FedRAMP compliant GovCloud. For the NEES survey, we will have the respondent names, email addresses, the organization name they are affiliated with, their county of affiliation and organization type stored in QuestionPro which will be used to send invitation and follow up emails. Email addresses uploaded to the QuestionPro for the purpose of sending survey invitations and email communication are owned solely by the survey administrator. An authorized Mathematica staff will be the designated programmer/survey administrator.

QuestionPro does not share any information uploaded to the system with any 3rd parties. Data collected through surveys is owned solely by the survey administrator. By default, the data is only accessible by providing a username and password and logging into the site. QuestionPro encrypts sensitive information using secure socket layer technology (SSL) and follows generally accepted industry standards to protect the personal information submitted to them, both during transmission and it is received. QuestionPro uses small files called cookies, stored on the respondent's device, to help customize or administer the survey experience. Cookies do not contain PII and are solely used for survey functionality. The survey data including the organization's name that the respondent is affiliated with, their county of affiliation and the organization type (without respondent names or email addresses), will ultimately be stored on secure drives and in restricted access folders that only those who are working with the data will have access to.

We may store some PID for the survey and key interview respondents, such as names, phone numbers, email addresses to support recruitment; 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 in the surveys or interviews, 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 of 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.**

July 5, 2024 - State KII Round 2 amendment:

Audio recording using WebEx/Zoom recording capabilities and DVR recorders will be conducted for the key informant interviews. 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 interview, we will transfer audio recordings from the WebEx/Zoom 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 WebEx/Zoom application and DVR device. The audio recordings will be used to create transcripts of the interviews, which will facilitate analysis of the data and summarizing 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 interview, we will immediately transfer audio recordings to our secure folder with access restricted to only those who are working with the data. We will then immediately erase the audio files from the WebEx/Zoom application and DVR recorders.
2. After receiving permission to do so from the respondent, we will only include in the audio recordings the first names (or pseudonyms) of the participants; that is, while we are recording the interviews, we will only use the first names of the participants, if given consent by the interviewee, so that the audio recordings will not include participants' last names.
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 interviews for transcription. We will receive transcripts through the secure transfer and save them to our secure password protected network drive folder with restricted access.
5. We will require the transcription service to delete the audio recordings and transcripts within 90 days of our receipt of the transcripts.

Previous amendment:

Key informant interviews

Audio recording using WebEx recording capabilities and DVR recorders will be conducted for the key informant interviews. 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 interview, we will transfer audio recordings from the WebEx 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 WebEx application and DVR device. The audio recordings will be used to create transcripts of the interviews, which will facilitate analysis of the data and summarizing 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 interview, we will immediately transfer audio recordings to our secure folder with access restricted to only those who are working with the data. We will then immediately erase the audio files from the WebEx application and DVR recorders.
2. After receiving permission to do so from the respondent, we will only include in the audio recordings the first names of the participants; that is, while we are recording the interviews, we will only use the first names of the participants so that the audio recordings will not include participants' last names.
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 interviews for transcription. We will receive transcripts through the 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.**

July 5, 2024 - State KII Round 2 amendment:

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 interviews, which will provide richer, more complete qualitative data than we would have if we instead only relied on note-taking during the interviews.

Previous Amendment:

We have designed the study to answer the evaluation questions and provide meaningful information for use at the local level while posing the least level of risk (minimal) to respondents as possible. . We have selected these methods for the following reasons:

- The network maps that result from the survey will be useful in determining where gaps in organizational relationships occur across the behavioral health ecosystem. If we completely anonymize the maps (that is, do not include organization sector labels), the information will not be as useful at the local level to inform future collaboration efforts.
- Audio recordings taken during county key informant interviews could be inadvertently lost or shared though we have multiple levels of protection from this risk built into our processes (and as described elsewhere in this application). The value of the audio recordings outweighs this minimal risk, because the recordings greatly enhance the quality of the data we are collecting by ensuring we capture exactly what the respondents said in the transcripts.

## **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.**

July 5, 2024 - State KII Round 2 amendment:

Participants in interviews might benefit from the opportunity to share their experience and inform improvements in the implementation of CYBHI, but otherwise would not experience direct benefits. CalHHS will use the data to make decisions about implementation of CYBHI. 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.

Previous amendment:

Network and Ecosystem Experiences survey

Organizations participating in the survey will benefit from receiving a summary of county-specific survey results, along with a report synthesizing survey and interview data. We anticipate this information will be useful at the county level to inform local collaboration efforts and efforts to create greater alignment and integration across the ecosystem. The report will also include a network map to show connections across the ecosystem.

Key informant interviews

We do not anticipate any direct benefit to the informants as individuals. County key informants may glean insights from the reports and data developed through this evaluation, which may inform internal understanding or decision making. There is also the potential that their sharing of experiences may inform improvements to CYBHI implementation, which could lead to program improvements.

## JUSTIFICATION OF RISKS

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

July 5, 2024 - State KII Round 2 amendment

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

Previous amendment:

As described in previous sections, risks to all participants are minimal. The data we are collecting will help inform the implementation of CYBHI and the state of California to achieve its ultimate goal of improving the well-being of children, youth, and their caregivers. We consider the level of risk to be reasonable in relation to the potential benefits to the communities served by the efforts under evaluation.

## 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.*

No identifiable materials

## 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 on an annual basis on data security policies and procedures relevant to this evaluation project, and they were each required to sign a confidentiality pledge. A copy of the document used to deliver the training is available on 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 hire, including the veracity of statements on CV, like education attained, certifications, and individuals stated as references to assure that 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 Qualitative data collection\_R2\_IRB  
Support Letter for Mathematica.pdf

Department Letter of  
Support

2023-108\_County 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 purposes of the Evaluation of CYBHI are to be used only 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 is 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.

Email addresses uploaded to QuestionPro for the purpose of sending survey invitations and email communication are owned solely by the survey administrator. QuestionPro does not share any information uploaded to the system with any 3rd parties. Data collected through surveys is owned solely by the survey administrator. At the end of each round the survey administrator will export the survey data to our restricted access folders at Mathematica and delete the survey responses in QuestionPro.

## **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 project director must authorize access to secure directories containing all project data. Mathematica's IT storage team grants access as authorized by the project director.

Previous amendment:

In QuestionPro, data collected through surveys is owned solely by the survey administrator. At the end of each round the survey administrator will export the survey data to our restricted access folders at Mathematica and delete the survey responses in QuestionPro.

## 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.**

July 5, 2024 - State KII Round 2 amendment

N/A

Previous amendment

The survey will not collect direct identifiers. All reported results will use survey weights, so no raw results from small cell sizes will be reported. The data will not be linked to any other sources.

## 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](#)*

Mathematica Data Security Letter-6.21.24.docx

Data Security Letter

Signed Mathematica Data Security Letter-2.27.24.docx

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.**

July 5, 2024 - State KII Round 2 amendment

Qualitative data:

For key informant interview, each respondent participant will be assigned a unique study ID number. We will save audio recordings and transcriptions on our secure server, and use filenames that use the study ID number and not names. We will store the unique study participant ID numbers in a separate subfolder within the restricted access folder on Mathematica's secure server from the interview 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 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 last names of any participants.

We will have the audio recordings transcribed by a transcription service, such as Way With Words. We will use a secure file transfer site to deliver the electronic audio recordings of the interviews for transcription. We will receive transcripts through the secure transfer and save them to our secure folder with restricted access. We will then maintain the transcripts within the secure drive.

Secondary data:

All publicly available secondary data we will use are de-identified.

## **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.**

July 5, 2024 - State KII Round 2 amendment

We do not anticipate collecting any confidential documents or PID from key informants. 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.

Network and Ecosystem Experiences survey

We do not anticipate collecting any confidential data in paper form/ documents. We will acquire consent electronically. We do not expect to receive PID in paper form for any administrative data.

Qualitative county data collection

We do not anticipate collecting any confidential documents or PID from key informants. 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 for both approaches to the county data collection. 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.**

July 5, 2024 - State KII Round 2 amendment

The qualitative key informant interviews will use electronic protocols without PID. WebEx/Zoom and DVR recordings sent to the transcription service may include first names (or pseudonyms). Once we receive transcripts from the transcription service, we will maintain transcripts within the secure drive. DVR recordings will be immediately uploaded to a secure Mathematica location as well as WebEX/Zoom recordings. The interview(s) on the DVR will be wiped as soon as upload is confirmed.

Protocols, interview 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 interviews 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 services destroy audio recording along with the written transcription and send written confirmation of destruction. Additionally, once we receive transcripts through the secure transfer and save them to our secure folder with restricted access, we will 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.

Previous amendment:

The Network and Ecosystem Experiences survey data without PID will be kept in restricted folders within a restricted drive on Mathematica's secure network behind a firewall.

The qualitative key informant interviews will use electronic protocols without



PID. WebEx 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 WebEX recordings. The Mathematica staff conducting and uploading interview(s) will wipe the interview(s) on the DVR as soon as the upload is confirmed.

Protocols, interview 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 interviews 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 services destroy audio recording along with the written transcription and send written confirmation of destruction. Additionally, once we receive transcripts through the 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 who have Mathematica key cards can enter the buildings. Visitors must request entry with a buzzer or pass through building security before accessing a Mathematica office. Visitors must also sign a log-in sheet stating name, date and purpose of visit; then are 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 at rest. All Mathematica servers are 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.**

July 5, 2024 - State KII Round 2 amendment

Qualitative data

For key informant interview, each respondent participant will be assigned a unique study ID number. We will save audio recordings and transcriptions on our secure server, and use filenames that use the study ID number and not names. We will store the unique study participant ID numbers in a separate subfolder within the restricted access folder on Mathematica's secure server from the interview 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 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 (or pseudonyms ) 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 Way With Words. We will use a secure file transfer site to deliver the electronic audio recordings of the interviews for transcription. We will receive transcripts through the secure transfer and save them to our secure folder with restricted access. We will maintain transcripts within the secure drive.

Network and Ecosystem Experiences Survey

At Mathematica, the survey data will be stored on secure drives and in restricted access folders. Those who are working with the survey data will have access to the name and type of organization the respondent is affiliated with and the county of affiliation. The data will not include the respondent's name or email address.

Personally identifiable information, including respondent names and email addresses, will be stored in QuestionPro until the conclusion of each round of data collection. This information will only be accessible to the survey administrator as long as the account stays active. At the end of each round the survey administrator will export the survey data to our restricted access folders at Mathematica and delete the survey responses in QuestionPro. The respondents' personally identifiable information will be stored separately from the survey data until the conclusion of the study.

### Key informant interviews

We will save audio recordings and transcriptions on our secure server. File names will include respondent sector (e.g., behavioral health, education, or child welfare) and position but will not include respondent names. Respondent names will be stored in a separate subfolder within the restricted access folder on Mathematica's secure server separate from the interview 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 respondent sector (e.g., behavioral health, education, or child welfare) and position but 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 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 the 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.

### **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 passwords with the following characteristics in order to make the passwords more difficult to guess/crack:

- Password change frequency: 30 days
- The minimum password length: 8 characters
- Not contain all or part of the user's account name
- The password must meet the system complexity requirements:
- Contain characters from three of the following four categories:
  - UPPERCASE characters (A through Z)
  - Lowercase characters (a through z)
  - Numerals (0 through 9)
  - Non-alphabetic characters (such as !, \$, #, %)

Employees are asked not to write the password down. Employees are asked not to tell passwords to colleagues or friends. If an employee must share a password (such as with a Mathematica computer technician), they are required to change their password as soon as possible afterwards.

Passwords should be creative. Employees are asked to not 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.

1. Please clarify "We will read elements of the consent script." You are using the script to obtain verbal consent, so all of it should be read, not just parts of it. 2. The consent script is missing language that asks for verbal consent to do the interview. You had this in your previously approved consent script. Please continue to use all previously approved text that is still relevant. 3. Please attach the approved script for the first round of state key informant interviews as well as the proposed script for the second round so that both are documented in this amendment.

07/20/2024 • John Schaeuble, PhD, MS • *Not Internal*

*See instructions and examples on [CPHS website](#).*

July 5, 2024 - State KII Round 2 amendment

Once selected, potential study subjects (i.e., key informant interviewees) will be contacted by email (and telephone if we do not have an email address for them or they do not respond to the email) to request their participation. In the email we will provide subjects with background describing the study, a high-level list of the topics to be discussed during the virtual 60-minute telephone interview, and explain that participation is voluntary and that the information they share will be confidential.

Once the subject agrees to participate, the interview team will coordinate a time for the virtual telephone interview, which will be conducted via WebEx or Zoom. The interview team will email an invitation that includes the confirmed date and time. We will also attach a copy of the verbal consent script to the invitation. We will read all elements of the consent script to participants at the start of the interviews, including that participation is voluntary, that the participants may stop the interview at any time or decline to answer any of our questions, that we will record the interviews with consent, and that we will keep information confidential. We will also explain risks and benefits. We ask for verbal consent before beginning the interview.

Previous amendment:

Network and Ecosystem Experiences survey

Potential respondents will click a link in the recruitment emails to access the web-based survey. Prior to beginning the survey, respondents will view a consent screen describing the survey purpose, length, voluntary nature, risks and benefits, and contact information for the study. Respondents must click that they "agree" to participate on behalf of their organizations before

they are able to access the survey.

### Key informant interviews

Once selected, potential study subjects (i.e., key informant interviewees) will be contacted by email (and telephone if we do not have an email address for them or they do not respond to the email) to request their participation. In the email we will provide subjects with background describing the study, a high-level list of the topics to be discussed during the virtual 60-minute telephone interview, and explain that participation is voluntary and that the information they share will be confidential.

Once the subject agrees to participate, the interview team will coordinate a time for the virtual telephone interview, which will be conducted via WebEx. The interview team will email an invitation that includes the confirmed date and time. We will also attach a copy of the verbal consent script to the invitation. We will read elements of the consent script to participants at the start of the interviews, including that participation is voluntary, that the participants may stop the interview at any time or decline to answer any of our questions, that we will record the interviews with consent, and that we will keep information confidential. We will also explain risks and benefits. We ask for verbal consent before beginning the interview.

## 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.*

<a href="#">County Key Informant Interview Protocol Introduction and Consent Script.docx</a>	Consent Form
<a href="#">Network and Ecosystem Experiences Survey Consent.docx</a>	Consent Form
<a href="#">State KII Recruitment_Interview Consent Form_Round 2.docx</a>	Consent Form

## HIPAA Determination

### HIPAA INSTRUCTIONS

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

### COVERED ENTITY

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

No

### HEALTHCARE PROVISIONS

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

No

### OTHER HIPAA CRITERIA

**Will the study involve other HIPAA criteria not listed above?**

No

### Amendment Changes

**List the pages and questions that have been changed.**

Most pages have changes. Responses that have changes have title July 5, 2024 - State KII Round 2 amendment

### 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\\_Cover Letter\\_State KII data collection.docx](#) 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.**

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