

View xForm - Project Application v6

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

Data entry

- Submitted 05/14/2025 4:16 PM ET by Annu van Bodegom

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

June 2025 cycle.

2. _____HSC Project_____

Requested de-identified HCAI data only to analyze trends. _____NO LOS from HCAI.???

Funding : State funded by CalHHS.
A LOS from CalHHS is attached.

The data collection and analyses will take place at Mathematica.
A DSL from Mathematica is attached.

05/08/2025 • Sussan Atifeh • Internal

Researchers from Mathematica have submitted this study (study of Certified Wellness Coaches) as part of the California Children and Youth Behavioral Health Initiative (CYBHI), funded by CalHHS under contract 2022-197-CYBHI. This study evaluates the new CWC profession by examining workforce diversity, training, impact, and sustainability in up to eight California counties. Researchers requested deidentified and aggregated state data from HCAI, though no personal identifying information is collected or used for recruitment. They Plan to conduct 32 virtual interviews with key stakeholders, including employers, supervisors, CWCs, and youth who received services. Findings will be published in a digital report on the CYBHI Evaluation website, helping policymakers assess the effectiveness of CWCs in supporting youth behavioral health.

05/09/2025 • 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.

Thanks,

05/09/2025 • Sussan Atifeh • *Not* Internal

Hi Ms. Kurtural.

You have been assigned as the SME for this project by the Chairs.

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

Thank you!

05/12/2025 • Sussan Atifeh • Not Internal

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

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Dan Friend, Ph.D

Email: DFriend@mathematica-
mpr.com

Business: (202) 264-3474

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

Mathematica Policy Research

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

Chicago

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

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

Illinois

Attach a copy of the PI's Curriculum Vitae.

Dan Friend_CV.docx PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

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

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

Dana M Petersen, MA, MPH, PhD

Email: dpetersen@mathematica-
mpr.com

Business: (510) 830-3703

Jenn Gordon, M.A.S.P.H.M

Email: JGordon@mathematica-
mpr.com

Business: (617) 715-6945

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

Dana Peterson_CV.docx Co-PI Curriculum Vitae

Jenn Gordon_CV.docx Co-PI Curriculum Vitae

ADMINISTRATIVE CONTACT

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

Annu van Bodegom

Email: AvanBodegom@mathematica- **Business:** (609) 297-4682
mpr.com

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

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

Rick McManus, MPP

Email: RMcManus@mathematica- **Business:** (202) 912-1027
mpr.com

OTHER RESEARCH STAFF

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

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

No answer provided.

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

False

Project Information

SUBMITTER

Application completed by:

Annu van Bodegom

Email: AvanBodegom@mathematica-
mpr.com **Business:** (609) 297-4682

PREVIOUSLY APPROVED EXEMPTION

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

No

PROJECT TITLE

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

Evaluation of the Children and Youth Behavioral Health Initiative – Study of Certified Wellness Coaches (CWC)

PROJECT SITE

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

Mathematica Policy Research, Inc.

STUDY PROCEDURES

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

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

05/09/2025 • Sussan Atifeh • Not Internal • Resolved

Data Registry
Interviews
Program Evaluations
Recruitment-Participant

TYPE OF RESEARCH REQUEST

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

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

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

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

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

Common rule/Human subjects

PROJECT TYPE DETAILS

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

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

Minimal Risk
Consent form
Assent form

VULNERABLE POPULATIONS

Indicate which vulnerable populations, if any, will be involved with this research. Check all that apply.

If vulnerable populations are not part of the research, choose "Not applicable."

Note regarding minors: in the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted.

Minors

Please click the link below to fill out the supplement involving children. After you've finished the form, you will need to save it locally and then attach in the space below.

Link to Children Supplemental Form

Checklist-For-Research-Involving-
Children_revised-CWC.pdf

Children Supplemental
Form

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.

State funded

Enter name of state-funded source.

CalHHS

EXPEDITED REVIEW CONSIDERATION

Please check the criteria below that you think your project meets to qualify for an expedited review. If none of these expedited criteria are appropriate for your project, choose 'not applicable'; your protocol will be reviewed by the full committee. Note that CPHS will make the final determination of whether the project meets the criteria for expedited review.

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

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

***The Departments within the California Health and Human Services Agency (CHHSA) are: Aging, Alcohol and Drug Programs, Child Support Services, Community Services and Development, Developmental Services, Emergency Medical Services Authority, Health Care Services, Mental Health, Public Health, Rehabilitation, Social Services and Statewide Health Planning and Development.*

Not applicable

ANTICIPATED PROJECT START DATE

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard.

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

06/16/2025

ANTICIPATED PROJECT END DATE

06/30/2026

Project Details

PURPOSE

Include a brief statement, less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public.

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

As part of the evaluation, we will develop the Certified Wellness Coach Report, that focuses on Certified Wellness Coaches. The Certified Wellness Coach (CWC) is a new profession that is helping to increase California's overall capacity to support the behavioral health and well-being of children and youth, as pursuant to the CYBHI authorizing legislation. The purpose of this study is to assess CYBHI's progress in achieving key workstream goals - building a workforce with knowledge of prevention and early intervention, creating a more diverse and representative workforce, and filling a gap in the behavioral health workforce pipeline. Findings will provide critical insights into CWC reach, use of CWCs, challenges and successes of implementation, strategies for sustaining this workforce, and qualitative perspectives on the perceived benefits of CWCs in supporting child and youth behavioral health in education and community settings. We will publish findings as a digital report on the CYBHI Evaluation website. The study will take place in organizations employing CWCs in up to eight California counties.

MAJOR RESEARCH QUESTION

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

The research questions to be addressed by this study are listed below.

1. What are the characteristics of the people who were awarded CWC scholarships?
2. What are the characteristics of the people who received CWC certification?
3. What are the characteristics of the organizations that received CWC Employer Support grants?
4. After employment, how are CWCs being integrated into educational settings?
5. After employment, what is the scope of services CWCs provide, and who uses those services?
6. What are the barriers and facilitators (B/Fs) to using CWCs at the state and local levels, and what strategies will help address the challenges?
7. What are staff and youth's perceptions of the benefits of CWCs?
8. What is required to sustain services provided by CWCs?

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

The CWC study will integrate primary interview data and secondary administrative data to understand the early efforts, progress, perceived benefits, and sustainability of the CWC workstream in a diverse set of organizations employing CWCs.

Primary interview data: We will conduct primary data collection through key informant interviews. In late summer/fall 2025, we will conduct up to 32 interviews. We will interview eight respondents in each of four categories: (1) leaders at organizations employing CWCs "employers"; (2) clinical supervisors overseeing the work of CWCs "supervisors"; (3) CWCs "CWCs"; and (4) students/youth (ages 14 to 17) who received services from a CWC, with parental consent if student/youth is a minor "students." While some employer interview respondents may be county level respondents (such as a representative at a County Office of Education), most interviewees, across types, will be local level respondents, working for various types of organizations that employ CWCs.

We will use four semi-structured interview guides, one for each of the four types of respondents. The core topics will align with the study research questions so that we can gather 4 viewpoints of how CWC efforts work in each of the up to 8 organizational settings included in the study. Interviews with adult respondents (employers, supervisors, CWCs) will last 60 minutes; interview with students will last 30 minutes. See the following documents linked to this applications: "CWC_employer guide", "CWC_supervisor guide", "CWC_CWC coach guide", and "CWC_youth guide."

All interviews will take place virtually, using a web-based platform (WebEx) with video or audio-only, depending on each respondent's preference. We plan to record the audio only so that we can submit the recordings for transcription by a transcription service – Way with Words. This will ensure complete and accurate data. We will include written language requesting consent to record the interviews in the consent script. We will destroy all recordings at the end of the study.

We will attach a copy of the consent script to the email and calendar invitations prior to each interview with an adult subject (employers, supervisors, CWCs) and a copy of the assent script for youth students. We will ask respondents to review the consent (or assent) script ahead of time. We will verbally review the consent (or assent) content and answer questions before initiating each interview and request verbal consent. If a respondent does not consent, we will terminate the interview. We will receive written consent from parents/guardians for all youth participants before sending calendar invitations to youth subjects. See "recruitment

details" section of this application for specific procedures.

We will obtain parental consent before scheduling or interviewing any youth participant respondents. We will ask the key employer contact at each organization included in the study if they would be willing to distribute a recruitment flier to youth at their organization (ages 14 to 17) who have received services from a CWC within the past year. The flier will let interested youth know that they can contact us via the study email (CYBHIEvaluation@mathematica-mpr.com) or a toll-free telephone number (855-743-8476). Alternatively, youth can ask staff at their organization or their parent/guardian to contact us on their behalf. The youth recruitment flier will briefly describe the study topics, state that participation is voluntary and confidential, and offer a \$25 VISA gift card upon completion of the 30 minute interview. The recruitment flier will also state that parental/guardian consent is required for participation of youth ages 14 to 17. When we receive notification of an interested student, we will reply and request contact information for a parent or guardian or ask that the student pass on a consent form to their parent/guardian. Parents/guardians will be asked to sign a form giving consent. The form will be emailed directly to the parent or the youth will email or give the form to parents on our behalf. We will also work with key contacts at organizations to coordinate parental/guardian consent as needed (for example printing consent forms as needed or giving them to parents on our behalf). We will ask that the signed parental/guardian consent form be returned to the study team via email. We will not schedule an interview with a youth until we receive a signed parental/guardian consent form. See "CWC_youth recruitment flier". See "CWC_parent consent" form linked below.

Once respondents agree to participate (and for youth, after parents give consent), we will coordinate a time for a virtual interview. The interview team will send a calendar invitation via email that includes the date and time of the interview, WebEx and telephone access information, and an attachment of the consent script as a PDF (for adults) and the assent script as a PDF (for youth). If the respondent does not have the ability to access the interview via WebEx or the computer, they can access the interview via a toll-free call in telephone number that will be listed in the invitation instead. The consent and assent scripts include 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 and telephone access information).

Before we begin any interview, we will read the consent form to adult subjects and assent form to youth subjects and ask for verbal agreement to participate in the interview. If verbal consent or assent is not provided, we will curtail the interview. See "CWC_adult subject consent form". See "CWC_youth assent form" linked below.

We will code the interview transcripts using the qualitative software package, Nvivo, and will analyze the data using common qualitative methods

such as descriptive and thematic analyses. We will produce a digital report for Cal HHS.

Secondary administrative data: In this application we are seeking approval for analyses we will perform on deidentified and aggregated data we will receive from Department of Health Care Access and Information (HCAI) at CalHHS. There will not be personally identifying information in the data we receive. We will only report counts and means from these data. We will use this de-identified and aggregated data to answer research questions 1 to 3 above and to describe the characteristics of (1) the people who were awarded CWC scholarships, (2) the people who received CWC certification, and (3) the organizations that received CWC Employer Support grants. Counts and means will be presented at the state and county level. If the same size is under 10 for any county, we will suppress the results. The Mathematica team communicated data requests to the HCAI team, which agreed to share deidentified and aggregated data; HCAI did not request or require a formal data use agreement given the data will be deidentified and aggregated.

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.

CWC_youth assent form.docx	Assent Forms
CWC_adult subject consent form.docx	Consent Form
CWC_parent consent form.docx	Consent Form
CWC_coach guide.docx	Protocol
CWC_employer guide.docx	Protocol
CWC_supervisor guide.docx	Protocol
CWC_youth guide.docx	Protocol
CWC_youth recruitment flier.docx	Recruitment Materials

RECORDING

Will audio or video recording occur?

Yes

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

We will record all interviews using the web-based meeting platform WebEx. Upon completion of each interview, we will immediately download WebEx audio files from the WebEx application and upload 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.

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. If a respondent does not give permission for us to use their first name, we will train interviewers to not use first names throughout the interview.

We will have the audio recordings transcribed by a transcription service—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 remove all 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 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

STATE DEPARTMENT DATA/SPECIMENS

Choose the department(s) from which you are requesting data and/or specimens and provide the formal name of the database or specimen registry. After you have selected the department from the drop down and entered the formal name of the database or specimen registry, click 'add' and repeat to add additional data and/or specimens if applicable.

Agency	Provide the formal name of the data base or specimen registry.
Department of Health Care Access and Information (HCAI)	Certified Wellness Coaches

Study Population

POPULATION DESCRIPTION

Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects such as: age; sex; ethnicity; and number of participants. Include requested participant number.

We will conduct primary data collection through virtual interviews. In late summer/fall 2025, we will conduct up to 32 interviews. We will interview eight respondents in each of four categories: (1) leaders at organizations employing CWCs "employers"; (2) clinical supervisors overseeing the work of CWCs "supervisors"; (3) CWCs "CWCs"; and (4) students/youth (ages 14 to 17) who received services from a CWC, with parental consent if student/youth is a minor "students." The study population for employers, clinical supervisors, and CWCs will be adults. The study population for students will include youth (ages 14 to 17) receiving CWC services and whose parents consent to their participation before we ask for student assent to participate.

We will select adult staff and leaders based on their implementation of CWC services, rather than on any demographic or other characteristic. We will select student/youth respondents for interviews on the basis of their receipt and engagement in CWC services and their age (no other demographic or personal characteristics will be considered). We expect all respondents in each of the four group will speak and read English. We expect each interview with adult respondents to last no more than 60 minutes. Interviews with student/youth respondents will last no more than 30 minutes. All interviews will take place virtually at a time that is convenient for the respondent.

The study population for the administrative data analysis varies depending on the HCAI database from which we will receive data. Deidentified and aggregated data on people who applied for CWC scholarships or certification will include adults, ages 18 to no limit. These data will be aggregated for the state overall, and for each of the 58 counties. Employer Support grant data will be aggregated at the organization level within each of California's 58 counties.

DATABASE DETAILS

List the database(s) to be used and the time period(s) being requested. This may include requests for future data that is not available at this time.

List the variables being requested, including a brief description of each variable.

Justify the need for each variable and for the quantity of data being requested.

You may also attach a list of variables on the next question.

Also address if participants will be involved in any other studies.

We also received your request to submit a Word or Excel document that lists all the variables that we will request from HCAI, including a justification for each variable request, and an explanation of how each variable will be used. We understand that this meets the IRB's request and that we will not need to submit formal data dictionaries.

We are in the process of reviewing available variables in HCAI's certified wellness coach-related systems. We anticipate being able to submit the list of variables (and justifications and usage) at the same time as we submit the letter of support.

If you have a list of variables with the details requested in the above question, attach that here. If you provided all details on the database in the question above, skip this question.

CWC_Support letter and data dictionary document.docx List of Variables

RATIONALE

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

The goal of the interviews is to obtain exploratory and descriptive information about the various respondents' experiences with the CYBHI CWC workstream and to identify insights into CWC reach, use of CWCs, challenges and successes of implementation, strategies for sustaining this workforce, and qualitative perspectives on the perceived benefits of CWCs in supporting child and youth behavioral health. The core topics will align with the study research questions so that we can gather 4 viewpoints of how CWC efforts work in each of the up to 8 organizational settings included in the study. Together the 4 viewpoints will provide a thick description of CWC implementation in specific organizational settings.

The goal of the analysis of the administrative data is to describe the reach and composition of the CWC workforce and the organizations that received grants to support their employment at the state and county level. This will help CYBHI know about the level of influence this workstream is having and progress is on track with expectations.

RECRUITMENT DETAILS

Describe how potential subjects will be identified for recruitment. Examples include: class rosters; group membership; individuals answering an advertisement; organization position titles (e.g., presidents, web designers, etc.). How will potential participants learn about the research and how will they be recruited (e.g., flyer, email, web posting, telephone, etc.)?

Important to remember: subjects cannot be contacted before IRB approval.

While waiting for IRB approval, we will begin identifying potential organizations and key organization employer contacts. We will not initiate recruitment of any study organizations or participants until after we receive IRB approval.

Identifying organizations: We will begin by identifying the up to eight organizations to include in the study, and will then identify one potential interview respondent within each of four categories (employer, supervisor, CWC, student) within each of those organizations. We will identify one organization that employed CWCs in the past year in each of up to eight counties. We will identify these organizations by reviewing internal CYBHI documents on CYBHI funding allocated through the CWC Employer Grants program, conducting internet research, and collaborating with known contacts at CalHHS and its departments to identify CWC employers. We will aim to identify six organizations that received CYBHI CWS Employer Grant funding to employ CWCs (4 organizations in educational settings and 2 organizations in community settings) and two organizations that employ CWCs without receipt of CYBHI funding (regardless of setting).

Recruiting organizations and key employer respondents: Once we identify the up to eight organizations employing CWCs, we will search organizational websites to identify a key employer contact, such as a director or lead of behavioral health services. We will reach out to the identified key employer contact to explain the study and invite their organization's participation. The recruitment email will explain the study and what participation involves. If the key employer contact agrees for their organization to participate in the study, we will then ask the key contact if they will personally participate as an interviewee or recommend another lead person at the organization who can speak to why the organization choose to employ CWCs. See "CWC_organization recruitment email" linked below.

Recruiting supervisor and CWC respondents: We will conduct snowball recruitment to identify clinical supervisor and CWC respondents within each organization. That is, we will ask the key employer contact to recommend a clinical supervisor to CWCs and a CWC for us to invite to participate in study interviews – and ask the key contact to share their emails with the study team. We will email potential respondents to explain the study and what participation involves (a one hour voluntary and confidential interview to learn the respondent's experiences with and opinions of the CWC role). See "CWC_supervisor and CWC recruitment email" linked below.

Recruiting students: Finally, we will ask the key employer contact at each organization if they would be willing to distribute a recruitment flier to youth at their organization (ages 14 to 17) who have received services from a CWC within the past year. The flier will let interested students know that they should ask their parent/guardian to contact us via the study email (CYBHIEvaluation@mathematica-mpr.com) or a toll-free telephone number (855-743-8476). Alternatively, parents/guardians can ask staff at their organization to contact us on the youth's behalf. The youth recruitment flier will briefly describe the study topics, state that participation is voluntary and confidential, and offer a \$25 VISA gift card upon completion of the 30 minute interview. The recruitment flier will also state that parental/guardian consent is required for participation of youth ages 14 to 17. When we receive notification of an interested student from a parent/guardian, we will reply and request that they sign a form giving consent for their youth to participate. We will also work with key contacts at organizations to coordinate parental/guardian consent as needed (for example printing consent forms as needed or giving them to parents on our behalf). We will ask that the signed parental/guardian consent form be returned to the study team via email. We will not contact youth directly or schedule an interview with youth until we receive a signed parental/guardian consent form. See "CWC_youth recruitment flier." See "CWC_parent consent form" linked below.

Once respondents agree to participate (and for youth, after parents give consent), we will coordinate a time for a virtual interview. The interview team will send a calendar invitation via email that includes the date and time of the interview, WebEx and telephone access information, and an attachment of the consent script as a PDF (for adults) and the assent script as a PDF (for youth). If the respondent does not have the ability to access the interview via WebEx or the computer, they can access the interview via a toll-free call in telephone number that will be listed in the invitation instead. The consent and assent scripts include 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 and telephone access information).

Before we begin any interview, we will read the consent form to adult subjects and assent form to youth subjects and ask for verbal agreement to participate in the interview. If verbal consent or assent is not provided, we will curtail the interview. See "CWC_adult subject consent form." See "CWC_youth assent form" linked below.

Attach copies of all recruitment materials.

CWC_adult subject consent form.docx	Recruitment Materials
CWC_organization recruitment email.docx	Recruitment Materials
CWC_parent consent form.docx	Recruitment Materials
CWC_supervisor and CWC recruitment email.docx	Recruitment Materials
CWC_youth assent form.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?

Yes

Compensation type

Gift card

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.

Student/youth interview participants will receive a \$25 electronic VISA gift card for a completed interview (30 minutes in length).

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.

We will conduct key informant interviews one time in the up to eight selected organizations in the summer/fall of 2025. We anticipate scheduling will occur in summer and early fall and that interviews will run from September to November 2025. Each participant will participate in interviews only once. Each adult interview will last up to 60 minutes. Each interview with a student/youth will last up to 30 minutes.

Risks and Benefits

RISK DESCRIPTION

Provide a description of possible risks to participants: physical, psychological, social, economic, loss of data security, and/or loss of confidentiality. Describe and justify whether the research is minimal risk or greater than minimal risk.

Risk level is minimal for interviews for all four respondent types.

The risk is very low for adult participants. The data we are collecting from adult key informants (employers, supervisors, and CWCs) is about their involvement, perceptions, and opinions of CYBHI and the CWC role and processes, and is not personal or sensitive. Adult participant groups (employers, supervisors, coaches) will answer questions about their professional roles, not personal experiences with receiving behavioral health supports.

Risks for students/youth (ages 14 to 17) participants are slightly higher than the risk to adult participants because youth are the only participant group that we ask questions related to their interactions with a behavioral health coach. . During interviews with youth, we will ask questions about the student's perceptions and experiences regarding interactions with and services received from CWCs. We will not ask questions about the youth's specific diagnoses or other potentially identifiable information. We will not ask youth questions about specific behavioral health conditions or questions about self-identity – such as sexual orientation or gender identity. For each student we invite to participate in the study we will first obtain consent from their parent or guardian. Students will then assent to participate before we begin asking interview questions. All interview participants, including youth can skip or decline any question at any time, or end the interview at any time. However, given the small psychological risk related to the topics for the youth sample, we will provide information for contacting 9-8-8 Suicide & Crisis Lifeline and SAMHSA Find Treatment service at the end of the interview should anything about the conversation suggest a need for information on how to connect to behavioral health supports. Both services are available 24 hours a day, year-round, in both English and Spanish.

Participation is voluntary for all adult and youth participants. Interview respondents may choose not to 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 adult participants and will seek informant consent from parents and guardians of youth participants, as well as assent from the youth.

A risk to interview respondent participants (of all four types) is of inadvertent loss of confidentiality. Mathematica's standard security procedures minimize this risk. Mathematica trains staff in security and privacy awareness as well as specific procedures and techniques for maintaining data confidentiality. Mathematica uses secure servers, a firewall, and computers that are password protected with full disk encryption. We

may store some PID 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 during the 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 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.

Risk level is minimal for administrative data analysis. All data sets we receive from HCAI will be deidentified and aggregated. We will present summary statistics for the state overall and each county. If needed, we will suppress results with small cell sizes (For example, in small and rural counties) to minimize the risk that individuals with very specific characteristics could be identified.

AUDIO/VIDEO RECORDING RISKS

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

Interviews: Audio recording using WebEx recording capabilities 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 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. 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 personally identifiable data (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.
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.

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.

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.

All study 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 findings from our study to make decisions about implementation of CYBHI. Student interview participants will benefit directly by receiving a \$25 VISA gift card payment for completion of a 30 minute interview.

The data collected might also be used by the California legislature and could help shape legislation aimed at creating or improving similar types of programs in the future.

JUSTIFICATION OF RISKS

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

Risks to subjects are minimal. The 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.

Administrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

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

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

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

HIPAA IDENTIFIERS

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

Name

All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)

Telephone numbers

Email address

TRAINING PROCEDURES

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

All Mathematica employees take mandatory, annual security and privacy awareness training. All staff working on this evaluation project who will have access to PID will receive training 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.

If you have requested data from HCAI for conducting this study, please obtain a Support Letter from HCAI and attach it in this section.

05/09/2025 • Sussan Atifeh • Not Internal

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_FS_CWC_STR_data collection_IRB
Support Letter for Mathematica.pdf
CWC_Support letter and data dictionary
document.docx

Department Letter
of Support
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.

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.

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

Describe appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

N/A

LINKAGES

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

No

DESTRUCTION OF PID VERIFICATION

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

Yes

DATA SECURITY LETTER

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

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

Signed_CYBHI_Mathematica Data Security
Letter_CWC.pdf

Data Security
Letter

Physical Safeguards

DATA PROTECTION

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

Yes

DATA DESTRUCTION

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

Yes

RETAINED DATA

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

data will be de-identified

Explain what identifiers will be removed and how.

For key informant interviews, 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 use 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 – 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.

DESTRUCTION METHODS

Describe how you will ensure the PID in paper form is disposed of through confidential means, such as cross cut shredding or pulverizing.

We do not anticipate collecting any confidential documents or PID from 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. We will contact study subjects using email or telephone.

MAILING

Indicate whether mailings of PID are sealed and secured from inappropriate viewing; and whether mailings of 500 or more individually identifiable records of PID in a single package, and all mailings of PID to vendors/contractors/co-researchers, are sent using a tracked mailing method, which includes verification of delivery and receipt, such as UPS, U.S. Express Mail, or Federal Express, or by bonded courier.

We will not have mailings of PID.

ELECTRONIC STORAGE

State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will ever be left unattended in cars or other unsecured locations.

The qualitative key informant interviews will use electronic protocols without PID. WebEx recordings sent to the transcription service may include first names. Once we receive transcripts from the transcription service, we will maintain transcripts within the secure drive. Recordings will be immediately uploaded to a secure Mathematica location.

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.

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.

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.

DISK STORAGE

State whether all disks with PID will be destroyed.

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

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

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

FIPS 140-2 COMPLIANCE: WORKSTATIONS

Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

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

FIPS 140-2 COMPLIANCE: LAPTOPS

Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

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

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

Indicate if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup recordings) are encrypted with software that is FIPS 140-2 compliant.

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

SECURITY PATCHES

Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

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

PASSWORD CONTROLS

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

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

Password change frequency: Does not expire

The minimum password length: 15 characters

Password history: Passphrase can be reused after 24 changes

- Password change frequency: In case of suspected compromise
- 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.

See instructions and examples on CPHS website.

Adult subjects (employers, supervisors, CWCs): Once selected, potential study subjects (i.e., key informant interviewees) will be contacted by email to request their participation. In the email we will provide subjects with background describing the study, a high-level list of the topics that will be discussed during the virtual 60-minute 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 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. If the subject declines to give consent, we will curtail the interview.

Youth student subjects: When we receive notification of an interested student from a parent or guardian, we will reply and ask the parent/guardian sign a consent form for their youth's participation. The form will be emailed directly to the parent. We will also work with key contacts at organizations to coordinate parental/guardian consent as needed (for example printing consent forms or delivering them to parents on our behalf). We will ask that the signed parental/guardian consent form be returned to the study team via email. We will not contact students directly schedule an interview with a youth student until we receive a signed parental/guardian consent form. See "CWC_parent consent form" linked in this application.

Once respondents agree to participate (and for youth, after parents give parents/guardian consent), 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 (for adults) and the assent script as a PDF (for youth students). The consent and assent scripts include 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).

Before we begin any interview, we will read the consent form to adults and

assent form to youth students and ask for verbal agreement to participate in the interview. If verbal consent or assent is not provided, we will curtail the interview. See "CWC_adult subject consent" linked in this application. See "CWC_youth assent form" linked in this application.

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.

CWC_adult subject consent form.docx	Consent Form
CWC_parent consent form.docx	Consent Form
CWC_youth assent form.docx	Consent Form

ASSENT PROCEDURES

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

See instructions and examples on the CPHS website.

Youth student subjects: When we receive notification of an interested student from a parent or guardian, we will reply and ask the parent/guardian sign a consent form for their youth's participation. The form will be emailed directly to the parent. We will also work with key contacts at organizations to coordinate parental/guardian consent as needed (for example printing consent forms or delivering them to parents on our behalf). We will ask that the signed parental/guardian consent form be returned to the study team via email. We will not contact students directly schedule an interview with a youth student until we receive a signed parental/guardian consent form. See "CWC_parent consent form" linked in this application.

Once respondents agree to participate (and for youth, after parents give parents/guardian consent), 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 (for adults) and the assent script as a PDF (for youth students). The consent and assent scripts include 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).

Before we begin any interview, we will read the consent form to adults and assent form to youth students and ask for verbal agreement to participate in the interview. If verbal consent or assent is not provided, we will curtail the interview. See "CWC_adult subject consent" linked in this application. See "CWC_youth assent form" linked in this application.

ASSENT FORMS

Attach copies of assent forms and any other documents or oral scripts used to inform potential research subjects about the study. See examples of consent and assent forms on the CPHS website. Be sure to include a concise explanation of key information for participants at the beginning of your assent form, as shown in the examples on the website. Also attach the Participant's Bill of Rights (download the revised version from the CPHS website).

Assent forms must be understandable to children who are 7-17 years of age. However, the same elements that are required in a consent form must be adequately covered in an assent form. The reading level must be age appropriate, and a shortened form may be needed for younger children or those with more limited reading ability. Thus, different versions of the assent form may be needed if the study involves children of significantly different ages. A question-and-answer format, as shown in the CPHS example of an assent form, may be especially appropriate.

CWC_parent consent form.docx Assent Forms
CWC_youth assent form.docx Assent Forms

HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

CYBHI_BudgetSummary_Task3.pdf Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

CYBHI_IRB_Mathematica_Cover Letter_CWC.pdf Cover Letter

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

Calculated Field for agency plus data set *(Internal)*

Department of Health Care Access and Information (HCAI): Certified Wellness Coaches

PI Signature for Coordinator Submission (Initial)
- Submitted 05/14/2025 7:34 PM ET by Dan Friend, Ph.D

PI Review

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

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

Yes

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

Signed Wednesday, May 14, 2025 7:34:20 PM ET by Dan Friend, Ph.D

Responsible Official Signature
- Submitted 05/02/2025 4:30 PM ET by Rick McManus, MPP

Responsible Official Signature

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

Yes, ready for submission to IRB.

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

Signed Friday, May 2, 2025 4:30:18 PM ET by Rick McManus, MPP

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

Internal IRB Screening

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

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

Yes

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

CPHS

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

Full Board Minimal Risk

Please provide a rationale for your level of review preliminary determination

This is a Human Subjects' Contacts study. Researchers from Mathematica have submitted this study (study of Certified Wellness Coaches) as part of the California Children and Youth Behavioral Health Initiative (CYBHI), funded by CalHHS under contract 2022-197-CYBHI. This study evaluates the new CWC profession by examining workforce diversity, training, impact, and sustainability in up to eight California counties. Researchers requested deidentified and aggregated state data from HCAI, though no personal identifying information is collected or used for recruitment. They Plan to conduct 32 virtual interviews with key stakeholders, including employers, supervisors, CWCs, and youth who received services. Findings will be published in a digital report on the CYBHI Evaluation website, helping policymakers assess the effectiveness of CWCs in supporting youth behavioral health.

Choose the CPHS Chair

Catherine Hess, PhD

Select the vice chair of the committee

Larry Dickey, MD, MPH, MSW

Assign to Cycle

June

Assign to cycle year
2025

Chair Review and Full Board Set-Up
- Submitted 05/14/2025 9:25 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2025-076

The office will complete the questions on this page and submit the form after the teleconference with the chairs regarding this project is completed.

Confirmation of level of review

Full Board Minimal Risk

Provide the rationale for the level of review determination

This project involves human subjects contact and is scheduled for review at the June 6th meeting. However, the Chairs have reviewed the study and believe there is a good chance that it may qualify for an Exempt or "Not Research" classification.

As the assigned SME, the Chairs have requested that you evaluate the project to confirm whether it meets the criteria for Exempt or "Not Research." If the study qualifies, please inform the CPHS staff via email, so they can notify the research team to withdraw the current application and resubmit under the appropriate "Not Research" or "Exempt" category. These applications will be reviewed by the Chairs through an expedited process, rather than a full board review.

Assign SME to study

Carrie Kurtural, JD

Enter the meeting date for this project

06/06/2025

SME Review

SME review

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

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

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

No answer provided.

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

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