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

View xForm - Project Application v6

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

Data entry
- Submitted 12/24/2025 10:37 AM ET by Wendy Hawkins, MPP

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

February 2026 cycle.

_____HSC-Full Board Review Project_____

12/17/2025 • Sussan Atifeh • Internal

• Non-English translation required
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• HIPAA Waiver Request
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12/17/2025 • Sussan Atifeh • Internal

Researchers from RAND have submitted this project to request a Common Rule/Human Subject review for the study. RAND was hired by California Department of Health Care Services (DHCS) to conduct an independent evaluation of the implementation process and outcomes of the CARE Act, as outlined in the California Welfare and Institutions Code section 5986. This evaluation aims to understand the implementation of the CARE Act at both the individual and system levels, and effectiveness of CARE at achieving its intended participant outcomes.

• Data-Source Departments:
DHCS---A LOS from DHCS is attached.
Researchers referenced data from DOJ and CalHHS. When asked for clarification, they resubmitted the application and explained that DHCS is the only state department "RELEASING" all required state data through the BAA. They noted that additional data may include claims data, Department of Justice data, or homelessness data. They also explained that they will conduct a survey with CARE respondents and petitioners. The survey aims to reach all CARE respondents, and they plan to work with DHCS, the Public Defender's Office, and county-level Behavioral Health leadership on recruitment strategies. They will receive contact information from DHCS and HMA through county-level reporting of the data dictionary. This information will be used, in collaboration with county Behavioral Health leadership, to conduct outreach and recruitment for both the survey and the qualitative interviews with CARE Act respondents and petitioners.

• Primary Site:
RAND---A DSL from RAND is attached.

• Linkage:
Yes---DHCS will link datasets securely for RAND and send to researchers in an SFTP folder. DHCS will link HMA's data dictionary with Medi-Cal claims and will link HCAI and DOJ data when possible.

• Funding:
Yes, by the California Department of Health Care Services (DHCS)

• End Product:
The end product will be an evaluation report that will be submitted to DHCS and CalHHS in September 2028.

• Non-English translation:
According to researchers, the Spanish Translations of the recruitment materials are not ready yet and the documents listed below are expected to be attached to this initial submission before releasing CPHS final approval letter:
—CARE Act Petitioner Survey Consent (Spanish version)
—CARE Act Petitioner Survey – Final Survey (Spanish version)
—CARE Act Respondent Survey Consent Script (Spanish version)
—CARE Act Respondent Survey – Final Survey (Spanish version)
—CARE Act Survey Recruitment Script (07-25-25) – Spanish version
—CARE Act Petitioner Recruitment Script (01-22-25) – Spanish version
—Spanish scales (they already attached a preliminary version, but CPHS will need the final translated version once the English survey is finalized)

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12/18/2025 • Sussan Atifeh • Internal

Since DHCS is requiring a HIPAA Waiver from CPHS, please complete all required sections on the "HIPAA Determination" page of this application by following the instructions below:

•Go to "HIPAA Determination" page (you can find this page using the dropdown menu at the top of the application)
•For the question in the "Covered Entity" box, select "Yes."
•Selecting "Yes" will prompt additional relevant sections.
•Under the "HIPAA Waiver" section, answer "Yes" to the question: "Are you requesting a waiver or alteration of HIPAA authorization?"
•This will generate the required questions for requesting a HIPAA Waiver from CPHS.

• • NOTE: Provide Variable Names
• When answering the HIPAA Waiver questions in this section, please provide a simple list of the variable names for which you are requesting approval. Only the names are needed—no descriptions or formatting. This list will be included in the final CPHS approval letter to specify the variables covered under the HIPAA waiver.
o Examples of variable names include:
—Date of birth
—Zip code
—Date of death

12/23/2025 • Sussan Atifeh • *Not* Internal • Resolved

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

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Melissa Labriola, PhD

Email: labriola@rand.org **Business:** (703) 413-1100

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

RAND

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

Enter the state in which the PI's institution is located.
Start typing in the state name to select the name from the list.
Virginia

Attach a copy of the PI's Curriculum Vitae.
M.Labriola CV 1.2025.docx PI Curriculum Vitae

Deleted Attachments: 1 (Most Recent: M.Labriola CV 1.2025.docx on 01/04/2026 10:31 PM ET)

CO-PRINCIPAL INVESTIGATOR (CO-PI)

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

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

Stephanie Holliday, Ph.D.

Email: holliday@rand.org **Business:** (310) 393-0411

Nicole Eberhart, PhD

Email: eberhart@rand.org **Business:** 3103930411x6083

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

Nicole_Eberhart_May 2025.pdf	Co-PI Curriculum Vitae
Stephanie Brooks Holliday CV NY.docx	Co-PI Curriculum Vitae

Deleted Attachments: 2 (Most Recent: Nicole_Eberhart_May 2025.pdf on 01/04/2026 10:31 PM ET)

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.

Wendy Hawkins, MPP
Email: whawkins@rand.org **Business:** (703) 413-1100

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.*

Peter Hussey, PhD
Email: hussey@rand.org **Business:** (617) 338-0259 ext. 8617

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.

Amy Shearer, PhD
Email: ashearer@rand.org **Business:** 1 310-393-0411 x7587
Alex Sizemore, MA
Email: asizemor@rand.edu **Business:** 1 703-413-1100 x5568
Samantha Matthhews, MPA
Email: smatthew@rand.edu **Business:** 1 310-393-0411 x7531
Avah Mousavi, PhD
Email: zmousavi@rand.org **Business:** 1 310-393-0411 x7152
Lou Mariano, PhD
Email: loum@rand.org **Business:** (703) 413-1100
Jonathan Cantor, PhD
Email: jcantor@rand.org **Business:** 310-393-0411 x6572

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

False

Project Information

SUBMITTER

Application completed by:

Wendy Hawkins, MPP

Email: whawkins@rand.org **Business:** (703) 413-1100

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).

CARE Court Program Independent Evaluation

PROJECT SITE

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

RAND

STUDY PROCEDURES

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

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

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

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

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

Thanks.

12/18/2025 • Sussan Atifeh • *Not* Internal • Resolved

Data Registry
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.

Please check with DHCS whether you must request a "HIPAA Waiver" from CPHS. If yes, please select "HIPAA Waiver" in this section and revise your responses in the "HIPAA Determination" page of this application. You can use the drop-down menu at the top of the application to find the relevant page.

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Please de-select "Informed Consent Waiver" in this section.

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

Non-English translation required
HIPAA waiver
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.

Individuals with Impaired Decision-Making Abilities

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
State funded

Enter name of state-funded source.
DHCS

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.

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. please select 2/6/2026 or a date following this date within a few weeks.

12/18/2025 • Sussan Atifeh • *Not* Internal • Resolved

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

02/09/2026

ANTICIPATED PROJECT END DATE

09/30/2028

Project Details

PURPOSE

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

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

• The main site(s) refer to the institution(s) responsible for the primary storage, receipt, and management of study data, as well as for ensuring data security and compliance with relevant regulations. This includes overseeing access controls, data encryption, and privacy safeguards. Typically, this is the Principal Investigator's and Responsible Official's institution, which houses and manages the servers through which the data is processed. Since in the case of an adverse event or loss of confidentiality, the PI and RO are accountable.

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RAND will conduct an independent evaluation of the implementation process and outcomes of the CARE Act.. This evaluation aims to understand the implementation of the CARE Act at both individual and system levels, and effectiveness of CARE at achieving its intended participant outcomes. The process evaluation will aim to answer these research Qs:
1: How prepared were counties to implement the CARE Act model?
RAND will explore the extent to which counties were prepared to implement CARE, including changes that were made to system workflows to accommodate CARE, and efforts made to increase capacity to implement.

2: How was CARE implemented?
RAND will assess factors that shaped the implementation of the CARE Act, whether or not CARE is reaching its intended target population, and to what degree it is being implemented with fidelity or adaptations. RAND will also explore the coordination and collaboration between state and local agencies.

EQ 3: What factors might be impacting the effectiveness of CARE?
RAND will assess the barriers and facilitators to implementation, as well as the strengths and weaknesses of its implementation.

The outcome evaluation will answer the following questions:

EQ 4: Did CARE participants increase their engagement in needed services?
RAND will assess the degree to which CARE participants increased their engagement in needed services, including housing, medication stabilization and mental health services.

EQ 5: Did CARE participants experience increased mental illness recovery and empowerment?
This will examine whether CARE participants experienced increased personal recovery and empowerment outcomes, and the degree to which these outcomes were experienced equitably.

The end product will be an evaluation report that will be submitted to DHCS and CalHHS in September 2028.

RAND (offices in Santa Monica, Pittsburgh, and Arlington, VA) will be responsible for the storage and management of data ensuring data security and compliance with regulations. In the case of an adverse event, our PI and RO will be responsible for reporting and following all protocols.

MAJOR RESEARCH QUESTION

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

This evaluation aims to understand the implementation of the CARE Act at both the individual and system levels, and effectiveness of CARE at achieving its intended participant outcomes. The process evaluation will answer questions related to the planning and implementation of CARE, including:

Evaluation Question (EQ) 1: How prepared were counties to implement the CARE Act model?
Through this evaluation question, RAND will explore the extent to which counties were prepared to implement CARE, including any changes that were made to system workflows to accommodate CARE, and any efforts made to increase capacity to implement.

EQ 2: How was CARE implemented?
RAND will assess the factors that shaped the implementation of the CARE Act, whether or not CARE is reaching its intended target population of individuals who are not already being served by county behavioral health providers, and to what degree it is being implemented with fidelity or adaptations. The evaluation will also explore the coordination and collaboration between state and local agencies.

EQ 3: What factors might be impacting the effectiveness of CARE?
In understanding the factors that might impact the effectiveness of CARE, RAND will assess the barriers and facilitators to implementation, as well as the strengths and weaknesses of its implementation.

The outcome evaluation will answer the following questions related to participant outcomes:

EQ 4: Did CARE participants increase their engagement in needed services?
As a key outcome of CARE, RAND will assess the degree to which CARE participants increased their engagement in needed services, including housing, medication stabilization and mental health services (referred to as the "three-legged stool"), among others. RAND will assess engagement in needed services and the degree to which access to these services was equitable.

EQ 5: Did CARE participants experience increased mental illness recovery and empowerment?
This evaluation will examine whether CARE participants experienced increased personal recovery and empowerment outcomes, and the degree to which these outcomes were experienced equitably.

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

Update on 12/22/2025:
Response to the comment below from Researchers:

[DHCS is the only state department "RELEASING" all needed state data throughout BAA. Through our BAA with DHCS, we will have access to HMA's data dictionary data (attached below), as well as HCAI data and Medi-Cal claims data.]

****

You have referred to requests for different datasets, like homelessness data, claim data, etc. that should be requested from different agencies. In other section, you referred to some linkage of HCAI and DOJ data that will be done by DHCS. Please identify the California state departments from which you are requesting data to conduct this study and specify the data sets requested from each department. A Support Letter must be provided by every department "RELEASING" data for your project and uploaded to the "Support Letter" section of this application before the project can be assigned for review.
Also, please clarify whether DHCS is the only state department "RELEASING" all needed state data for your project since only one support letter from DHCS is attached in the "Support Letter" section of this application.
Thanks.

12/18/2025 • Sussan Atifeh • *Not* Internal • Resolved

Update on 12/22/2025:
Response to the comment below:

[We will receive contact information from DHCS and HMA through county level reporting of the data dictionary. This information will be used, in collaboration with county BH leadership, to conduct outreach and recruitment for our survey and for our qualitative interviews of CARE Act respondents and petitioners.]

****

Please clarify in a separate paragraph whether any state-level datasets of the ones referred by you in this application (e.g., DHCS claims data, Department of Justice data, homelessness data, or other state-maintained records) will be used to directly identify or contact study participants. This clarification is very important for CPHS to determine the appropriate level of review.

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You selected "Non-English Translations" under the Study Procedures section on page 2 and attached one Spanish-translated document. Please clarify which study documents will be translated into Spanish for use in this project. List each document here using the exact file name(s) you used for the attached recruitment materials.

12/18/2025 • Sussan Atifeh • *Not* Internal • Resolved

INTERNAL NOTE:

According to Researchers: Spanish documents that must be attached before CPHS approval

• CARE Act Petitioner Survey Consent (Spanish version)
• CARE Act Petitioner Survey – Final Survey (Spanish version)
• CARE Act Respondent Survey Consent Script (Spanish version)
• CARE Act Respondent Survey – Final Survey (Spanish version)
• CARE Act Survey Recruitment Script (07-25-25) – Spanish version
• CARE Act Petitioner Recruitment Script (01-22-25) – Spanish version

• • Spanish scales (they already attached a preliminary version, but CPHS will need the final translated version once the English survey is finalized).

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12/23/2025 • Sussan Atifeh • Internal

Our evaluation will utilize a mixed methods approach, analyzing both quantitative data and qualitative data. Our team will work with DHCS to acquire data for analysis. This will include data collected by Health Management Associates (HMA), the technical assistance provider for the counties, as well as supplemental sources that we will obtain through our BAA with DHCS. DHCS is the only state department "RELEASING" all needed state data through out BAA. Additional data could include claims data, department of justice data, or homelessness data. Additionally, we will conduct a survey with CARE respondents and petitioners. The survey will try to reach all CARE respondents and we will work with DHCS, the public defenders' office, and county level Behavioral Health leadership on recruitment strategies. We will receive contact information from DHCS and HMA through county level reporting of the data dictionary. This information will be used, in collaboration with county BH leadership, to conduct outreach and recruitment for our survey and for our qualitative interviews of CARE Act respondents and petitioners. For our qualitative interviews, we will pick a subsample of 12 counties across California to work with. We will also conduct qualitative interviews with CARE respondents and petitioners. Our goal is to interview 20 CARE participants and 20 petitioners from each of the selected counties. We will work with county level partners, such as BH leadership and anticipate that partners will share information about the interview procedure with clients, and then will share the participant's preferred contact information for individuals who are interested in learning more about the evaluation with RAND. We will conduct outreach using the prospective interviewee's preferred contact method. We will also conduct staff interviews with leadership and staff at state-level organizations, such as DHCS, HMA, CalHHS, and Judicial Council. At the county level, we will speak with BH leadership and staff, public defenders, judges, and other local implementation partners. I have attached our evaluation plan, our qualitative interview protocols, and our survey for further review.

The survey will be offered in English and Spanish. We have not translated all of our documents into Spanish yet, but the documents that will be in Spanish include: CARE Act Petitioner Survey Consent, CARE Act Petitioner Survey_FINAL, CARE Act Respondent

Survey Consent Script, CARE Act Respondent Survey_FINAL, CARE Act Survey Recruitment Script 07-25-25, and CARE Act Petitioner Recruitment Script 01-22-25 (1). I have attached Spanish scales, which is a translation of the scales from the Respondent survey, but it is not a final translation, since we have not received approval, we have not had our translator translate all of the documents, but we gathered the scales in Spanish as a preliminary step.

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.

CARE Act Petitioner Survey Consent.docx	Consent Form
CARE Act Respondent Survey Consent Script.docx	Consent Form
CARE Client Interview Consent Script.docx	Consent Form
CARE Petitioner Interview Consent Script.docx	Consent Form
DHCS HIPAA Waiver Email.png	HIPAA Documents
CARE Act Evaluation Plan	Other Documents
CARE Act Petitioner Interview Recruitment Script 01-22-25 (1).docx	Other Documents
CARE Act Survey Recruitment Script 07-25-25.docx	Other Documents
Survey Scales - Spanish.xlsx	Other Documents
CARE Act Petitioner Survey_FINAL.docx	Questionnaires
CARE Act Qualitative Interview Guide State Level	Questionnaires
CARE Act Respondent Survey_FINAL.docx	Questionnaires
CARE Act Staff Qualitative Interview Guide	Questionnaires
CARE Respondent and Petitioner Interview Protocols_FINAL.docx	Questionnaires

Deleted Attachments: 14 (Most Recent: Survey Scales - Spanish.xlsx on 01/04/2026 10:31 PM ET)

RECORDING

Will audio or video recording occur?

Yes

Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).
We will audio record qualitative interviews after obtaining verbal consent from state and county level staff as well as CARE respondents and petitioners. Interviews will take place on Teams or Zoom.Gov, which are both RAND approved secure sites. Zoom.Gov is utilized by RAND for a higher level of protection, and we will use a RAND provided Zoom.Gov account for our interviews with CARE respondents and petitioners. All interviewees can decline the audio recording. We will rely on a note taker in these instances. The recordings will be stored on a RAND approved secure device and not shared with anyone outside of our research team. All recordings will be securely deleted at the end of the evaluation. We will scrub transcripts of identifying information and will aggregate findings, so that no individual can be identified in final reports or presentations.

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.

> is HCAI providing research staff, funding and/or patients from State mental hospitals for this project?
> If not, please de-select it.
>
> 12/22/2025 • Sussan Atifeh • *Not* Internal • Resolved

DHCS: Department of Health Care Services

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.

> Please delete the second row. Instead, in the first row, add the formal name of the HCAI-linked dataset that DHCS will be providing to you in the right-hand column. "HCAI" refers to the department, not the formal name of the dataset, so the table should list the actual dataset name rather than the agency name.
>
> 12/22/2025 • Sussan Atifeh • *Not* Internal • Resolved

Agency	Provide the formal name of the data base or specimen registry.
Department of Health Care Services	CARE Act Data Dictionary
Department of Health Care Services	MID/DSS Claims
Department of Health Care Services	MEDS_MISDSS Claims
Department of Health Care Services	Cal OMS Data

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.

1. County and State level qualitative interviews: RAND will interview a range of staff implementing CARE within each selected county, as well as DHCS and other relevant state-level agencies. We will select 12 counties across California for county level interviews, and will interview 15-20 people per county to reach saturation. We hope to speak to 10-15 state level partners. Individuals' age and sex does not impact who we recruit for these interviews; we aim to speak with people with experience implementing the CARE Act. We will we will work with DHCS and Health Management Associates (HMA) staff to identify county behavioral health leads who will be a primary point of contact. Given behavioral health agencies' key role in implementing CARE at the county-level, we will work closely with leadership to identify staff within their agency, as well as leadership at courts, other county departments, and service providers. We hope to speak to 180-220 individuals across the state and county.
2. CARE Respondent Qualitative Interviews: We will recruit participants across the stages of the CARE process, aiming for at least 5 elective clients, 5 respondents with a voluntary CARE agreement, and 10 CARE respondents with a formal CARE plan from each county. We are also interested in understanding the participant experience at different points in their trajectory through the program and will therefore aim to interview people early in their experience (e.g., CARE process initiation) as well as those who are later in the experience (e.g., treatment, housing, and support). We will coordinate with county-level implementation partners to identify participants who are willing to participate in an interview. We will share any details related to inclusion or exclusion criteria with implementation partners to guide this process (e.g., length of time in the program, ability to engage in an interview). All interviewees will be over the age of 18. Their sex and ethnicity will vary depending on each counties' CARE enrollees. We hope to speak to 20 individuals in each of our 12 partnering counties, totaling 240 interviews.
3. Petitioner Qualitative Interviews and Survey: RAND will interview CARE petitioners in selected counties to learn more about the process of submitting a petition, petitioner perceptions of the post-petition process, and their perceptions of the effectiveness of the CARE Act model. Petitioners may include behavioral health providers, first responders, law enforcement, and family members of those being petitioned. All petitioners will be over 18. Their sex and ethnicity will vary as will their relationship to the individual being petitioned. We hope to speak to 20 petitioners per county, totaling 240 individuals. We will recruit petitioners for the survey to learn about their experiences with the CARE process. We will broadly invite as many petitioners as possible. Their age will be over 18; their sex and ethnicity will vary depending on who the population of petitioners is in each county.
4. CARE Respondent Survey: RAND will conduct a survey of CARE participants in order to understand the CARE process and outcomes from clients' perspectives. The survey will be conducted at two points in time, early and late in their CARE participation journeys. In this pre-post design, participants will be compared to themselves in order to determine whether they experience improvement in outcomes over time. Survey participants will include individuals who have an established CARE plan and may also include individuals who have a CARE agreement but not a plan (Voluntary CARE Agreement), and those who voluntarily entered treatment or services after a CARE petition dismissal (Elective Clients). We intend to broadly invite all individuals with CARE plans to participate. We will recruit as many CARE respondents as possible. All interviewees will be over 18; their sex and ethnicity will vary based on who is enrolled in the CARE Act.

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.

please attach all lists of requested variables (using descriptive names) by attaching the formal data dictionaries in the "DATABASE DETAILS" section.
In the attached list(s) you need to provide a brief explanation to justify requesting each variable and to show the use of the variables. Thanks.

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

12/22/2025 • Sussan Atifeh • *Not* Internal • Resolved

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.

Through our BAA with DHCS, we will have access to HMA's data dictionary data (attached below), as well as HCAI data and Medi-Cal claims data, DSH, and Cal-OMS.

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.

CARE-ACT-Data-Dictionary-2025.pdf	List of Variables
Data Set Request_RAND_CalOMS.xlsx	List of Variables
Data Set Request_RAND_DSH.xlsx	List of Variables
FullDataSetLayoutSpecification_UPDATED 08-28-24.xlsx	List of Variables
RAND Requests for HCAI PDD ED Data CY 2018-2023 update 03-10-2025.xlsx	List of Variables

Deleted Attachments: 5 (Most Recent: RAND Requests for HCAI PDD ED Data CY 2018-2023 update 03-10-2025.xlsx on 01/04/2026 10:31 PM ET)

RATIONALE

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

An evaluation of the CARE Act is required in accordance with California Welfare and Institutions (W&I) Code section 5986.
Section 5986 included here for reference: (a) An independent, research-based entity shall be retained by the department to develop, in consultation with county behavioral health agencies, county CARE courts, racial justice experts, and other appropriate stakeholders, including providers and CARE court participants, an independent evaluation of the effectiveness of the CARE Act. The independent evaluation shall employ statistical research methodology and include a logic model, hypotheses, comparative or quasi-experimental analyses, and conclusions regarding the extent to which the CARE Act model is associated, correlated, and causally related with the performance of the outcome measures included in the annual reports. The independent evaluation shall include results from a survey conducted of program participants. The independent evaluation shall highlight racial, ethnic, and other demographic disparities, and include causal inference or descriptive analyses regarding the impact of the CARE Act on disparity reduction efforts.
(b) The department shall provide a preliminary report to the Legislature by December 31, 2026, and a final report to the Legislature by December 31, 2028. The department shall post the preliminary and final reports on its internet website.
(c) Each county behavioral health department, each county CARE court, and any other state or local governmental entity, as determined by the department, shall provide the required data to the department, in a format and frequency as directed by the department.
(d) A report to be submitted pursuant to this section shall be submitted in compliance with Section 9795 of the Government Code.

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.

1. County and State Level Interviews:At the state level, we will interview leadership and staff at agencies involved in the planning and ongoing implementation of CARE. This will include DHCS, HMA, the California Health and Human Services Agency (CalHHS), and the Judicial Council of California (JC). We will also engage a range of other state-level entities, which may include CARE Act Working Group members such as the Legal Aid Association of California, Disability Rights California, Anthem Blue Cross, and the California Department of Veterans Affairs. We will work with DHCS and HMA staff to identify specific agencies to ensure that we capture perspectives of state-level implementation, as well as coordination between the state and counties, and between counties. We will coordinate with DHCS and HMA to identify points of contact to interview at each organization. From each county's Behavioral Health agency, we will interview leadership and staff involved in managing the program, completing CARE 101 forms, conducting psychosocial evaluations, and providing direct services to clients, including clinicians, case managers, peer support specialists, and housing support specialists. From county court systems, we will interview judges, public defenders, and county counsel attorneys assigned to CARE. Other county departments and community-based partners involved in CARE will also be engaged, including housing departments, outreach teams, contracted service providers, and advocacy organizations, such as the National Alliance on Mental Illness (NAMI).
To recruit staff participants, we will work with DHCS and Health Management Associates (HMA) staff to identify county behavioral health leads who will be a primary point of contact. Given behavioral health agencies' key role in implementing CARE at the county-level, we will work closely with leadership to identify staff within their agency, as well as leadership at courts, other county departments, and service providers. After interviewing leadership at each of these organizations, we will request interviews with staff. If we learn of additional individuals in roles relevant to implementation, we will also follow-up with those implementation partners, consistent with a snowball sampling approach.
2. CARE Respondent Qualitative Interviews: We will coordinate with county-level implementation partners to identify participants who are willing to participate in an interview. We will share any details related to inclusion or exclusion criteria with implementation partners to guide this process (e.g., length of time in the program, ability to engage in an interview), while also being careful to educate implementation partners about the importance of referring clients who may have had a range of experiences with CARE, not just those who were perceived as particularly engaged or "successful" in the program. When working with implementation partners we will also encourage them to refer clients who reflect the diversity of the CARE participants they typically work with in terms of identity and lived experience. For example, if the research team learns during initial discussions with implementation partners that many of the CARE participants they work with are unhoused, then we will encourage our implementation partners to help connect us with CARE participants who can speak to that lived experience. We will strive to ensure our sample includes participants from diverse backgrounds to adequately reflect the community's diversity and address potential disparities in health outcomes. We anticipate that partners will share information about the interview procedure with clients, and then will share the participant's preferred contact information for individuals who are interested in learning more about the evaluation with RAND. We will conduct outreach using the prospective interviewee's preferred contact method, which we anticipate will include telephone (calls, text messages, and/or email). An important consideration related to the recruitment of CARE participants is the acuity of their symptoms and whether they can provide informed consent for participation. Therefore, RAND will work closely with implementation partners to ensure that participants are being reached at a stage at which they can provide informed consent.
3. CARE Petitioner Qualitative Interviews and Surveys:To the extent possible, we will

leverage data submitted by counties to HMA to understand the frequency with which petitions are submitted by each potential group (e.g., family members, roommates, law enforcement, hospitals), and then aim to recruit a sample that is representative of the composition of petitioners within that county. We plan to work with local implementation partners for the recruitment of petitioners. For example, we may be able to leverage connections with the local behavioral health departments or court self-help staff to recruit petitioners who may be friends or family members. If government agencies like behavioral health departments, hospitals and law enforcement are a substantial portion of petitions based our analysis of petitioner HMA data, then we will reach out directly to these agencies to recruit participants.
4. CARE Respondent Survey: Participants will then be recruited through a two-pronged, three-stage process. Primary recruitment will be through contacting the petitioner, who we will ask for assistance in locating the CARE participant (as petitioners are more likely to have stable contact information). Secondary recruitment will be via directly contacting the individual served by CARE. As described in the survey design section, there will be three stages of recruitment: starting with e-mail recruitment, moving to phone recruitment as needed, then finally in-person recruitment in selected counties for those CARE participants we are unable to recruit by either email or phone.

Attach copies of all recruitment materials.

CARE Act Interview Recruitment Flyer	Recruitment Materials
CARE Act Petitioner Interview Recruitment Script	Recruitment Materials
CARE Act Respondent Survey Consent Script	Recruitment Materials
CARE Respondent Interview Recruitment Script	Recruitment Materials
CARE Respondent Survey Flyer	Recruitment Materials
State and County Staff Recruitment Email	Recruitment Materials

Deleted Attachments: 10 (Most Recent: CARE Respondent Interview Recruitment Script on 01/04/2026 10:31 PM ET)

SCREENING

Will subjects be screened prior to entry into the research?

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.
Participants will also be asked to provide informed consent to participate in any data collection efforts (interviews or surveys), in which they will be informed about the study aims, risks and potential benefits, expectations for confidentiality, and contact information for RAND IRB and the study director. Participants will have the option to decline to participate, decline to answer any questions they prefer not to, and to withdraw consent from the study and have their data deleted at any time. An important consideration related to the recruitment of CARE participants is the acuity of their symptoms and whether they can provide informed consent for participation. RAND will work closely with implementation partners to ensure that participants are being reached at a stage at which they can provide informed consent.

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.
County and State level staff will not be compensated.
Petitioners will receive a $50 gift card for participating in a qualitative interview.
CARE Act respondents will receive a $50 gift card for participating in a qualitative interview.
CARE Act respondents will receive a $50 gift card for completing the baseline survey and then $100 for completing the follow-up survey 9 months later.

STUDY DURATION

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

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

This is a 5 year evaluation. County and State level staff will be interviewed up to 2 times and each interview will last 45-60 minutes. Total participation is 1.5-2 hours.
Petitioners will be interviewed once for 45-60 minutes. The petitioner survey will take 15-20 minutes. Not all petitioners will complete both interviews and surveys. Total time is up to 1 hour and 20 minutes.
CARE Act respondents will be interviewed once and the interview will take 30-45 minutes. The survey will take up to 30 minutes for baseline and for follow-up. Not all respondents will complete both the interview and the survey. Total participation time is 2 hours.

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.

There is a small risk that some of the questions we ask could be upsetting for the CARE Act respondents, as we will be asking about the services they receive and their experience with the CARE process. They can skip any questions they do not feel comfortable with and still be part of this evaluation, and they can stop the interview or survey at any time with no consequence to their services.
There is a potential risk of breach of confidentiality. We believe this is a minimal risk and unlikely to occur. The data will not include personal identifiers and will be stored on RAND secure, password protected devices.
All quantitative data is downloaded in a cold room on RAND premises, and then de-identified before being stored on a RAND approved, secure device.

AUDIO/VIDEO RECORDING RISKS

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

One potential risk is a breach of confidentiality. While such a breach would be serious, it is unlikely to occur because the data will not include personal identifiers but will instead be associated with a scrambled person ID and will be stored with appropriate security measures as specified in the RAND data storage, transfer, and disposal matrices. Additionally, RAND office computers are password protected, ensuring that only the designated staff member with a personal username and password can access data on an office computer. Laptop computers at RAND are equipped with encrypted hard disks.

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.

We do not anticipate adverse effects. If a participant does not want to answer a question, they can skip the question or end the interview or survey. No services are being provided.

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.

As stated in the legislation, the evaluation must consult with county behavioral health agencies, county CARE courts, racial justice experts, and other appropriate stakeholders, including providers and CARE court participants, to conduct a robust independent evaluation of the effectiveness of the CARE Act. We feel it is important to hear from CARE respondents themselves about the program they are engaged with, and will obtain consent, explain the process, and ask questions about their experiences to provide the most complete picture of their experiences in our final report.

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.

While there are no direct benefits from participation, respondents are compensated for their time and get to share their experiences with the CARE Act, which could benefit future CARE respondents.

JUSTIFICATION OF RISKS

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

We believe the risks are justified because we store our data very securely and because it is important to hear from the CARE respondents about their experiences in the program. Some examples of our data security are shared below:
1. Data will be stored on a secure, password-protected RAND server. Access to the specific directory will require a username and password and will be restricted to evaluation team members. Data may not be stored in any other location
2. Identifiable data will be stored on a cold room computer for the duration of the project.
3. Survey Data Process and Procedures: SRG will create and manage a database with respondents' information, including respondent's name, enrollment date, baseline interview completion date and study ID number. Only SRG staff on this project will have access to this database. The database will be stored on a server on the SRG Secure Network Segment. Computers that support SRG Operations are located on isolated network segments on RAND's internal network. SRG computers have no Internet access, e-mail, and file or print sharing outside of the secure segment. All ports that provide access to the SRG segment are locked in offices in a secure facility. Access to the RMS database is restricted through password protection. Access to associated electronic documents is protected through Windows file permissions. Once the project is over, the database will be destroyed.
4. Under no circumstances may these data be stored on the open web or reside outside of a RAND-owned resource.

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

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

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

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

HIPAA IDENTIFIERS

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

Name
Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
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
Social Security Number
Medical record number
Health plan beneficiary number

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.

Project staff will undergo training on project-specific data sensitivity and data safeguarding practices as required. Staff will annually review the inventory of sensitive data and the associated data safeguards.

STAFF VETTING PROCEDURES

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

> Your response describes the background check for one staff member, but CPHS needs information about the procedures used to vet all staff who will have access to PID. Please describe RAND's standard background check or reference check process for personnel with access to sensitive data and confirm that all project staff with PID access will undergo these procedures."
>
> 12/18/2025 • Sussan Atifeh • *Not* Internal • Resolved

Our Quantitative Analyst lead has undergone a background and reference check before being hired at RAND, and has over 15 years of experience at RAND working with highly sensitive data. They maintain all security trainings required by RAND, including how to access and utilize a cold room and human subjects training. All staff at RAND undergo a background check prior to being hired at RAND. All staff at RAND complete annual data safety and security trainings and have human subjects training. The quantitative analyst is the only staff person who goes into the cold room to de-identify the 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.

DHCS Letter of Support Department Letter of Support

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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 will be destroyed at the end of the evaluation, or throughout the project if allowable. In all cases, data transfer, storage, and disposal will be accomplished in accordance with the guidelines on RAND's data security requirements.

CONFIDENTIALITY OF PUBLISHED DATA

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

All reports and publications will be reviewed by the Principal Investigators (PIs) to ensure adherence to publication standards. These standards are designed to ensure that tabular and graphical presentations of the data do not compromise the confidentiality of individuals.

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?

In order to satisfy the legislative requirements, our evaluation team needs to conduct robust quantitative analyses, which includes utilizing available datasets and linking data to measure outcomes for CARE respondents.

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.

Data access is limited to those with a need to know for the purposes of conducting the evaluation.

UNIQUE IDENTIFIERS

If applicable, justify why unique identifiers, other than social security numbers, cannot be used.

Through our BAA with DHCS, datasets will be linked, and social security numbers are utilized to ensure accuracy of data linkage.

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.

Our team is working with DHCS and following their guidance per suppression of small cell sizes. Details included: DHCS is utilizing the following guide and score card (page 18) to identify if some of the data needs to be suppressed: https://www.dhcs.ca.gov/dataandstats/Documents/DHCS-DDG-V2-2.pdf. After speaking with the director's office multiple times, we know that not all data requires suppression.

Per CDO, all data is scored to determine if suppression of counts <11 is required based on the DHCS DDG (link above).
Any data that receives a score higher than 12, will require suppression of small counts (1-10).

Variables scored:
• Events (numerator)
• Age – is age a variable within the data or program that data is being reported for (e.g. CCS, CHIP – children)
• Sex or SOGi
• Race/Ethnicity
• Language
• Time Period (monthly, annual, etc.)
• Geography (is data based on Service or Member Residence
• How many variables interact in the data

LINKAGES

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

Yes

Identify all data sets and each of the variables to be linked, with a brief description of each variable and justification for each linkage. If there is an extensive list, you may attach that list in the next question and indicate such here.
I have attached variable lists, which include justifications that our evaluation team worked on together with DHCS and HMA. Since we have a BAA with DHCS, their data team will link datasets securely for us and send to us in an SFTP folder. DHCS will link HMA's data dictionary with Medi-Cal claims, and will link HCAI and DOJ data when possible. Our quantitative lead downloads the data in a secure cold room and de-identifies the data and then re-uploads to a RAND secure location.

Attach a copy of the document detailing all data sets and each of the variables to be linked. If you provided this information in the answer to the above question, skip this question.

CARE-ACT-Data-Dictionary-2025.pdf	Other Documents
Data Set Request_RAND_CalOMS.xlsx	Other Documents
Data Set Request_RAND_DSH.xlsx	Other Documents
FullDataSetLayoutSpecification.xls.xlsx	Other Documents
RAND Picks for HCAI Emergency Dept Data.xlsx	Other Documents
RAND Requests for HCAI PDD ED Data CY 2018-2023 update 03-10-2025.xlsx	Other Documents

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Will a third party be used for data linkage?
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*

Data Security Letter Data Security Letter

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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.
Data with PID (names, contact information, identification numbers) will be processed in a cold room (an air locked computer, which is not connected to the internet), and de-identified (all PID removed). Only de-identified data will leave the cold room for analysis on a RAND secure computing environment.

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 will destroy all data at the end of the evaluation.

FAXING

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

We do not use faxes.

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.

Any mailings sent out will be to invite CARE respondents or petitioners to participate in the survey. There will not be 500 individually identifiable records ever in a single package. Any mailings will be sent using a tracked mailing method.

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.

All RAND computers are password protected and require duo-authentication to log in. Computers are not stored in unsecure locations.

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.

The cold room has controlled access procedures in place, no internet available, and security training is required for RAND staff to access the cold room.

SERVER SECURITY

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

Unencrypted data is stored in a secure SFTP folder that DHCS shared with RAND approved staff. RAND approved staff downloads the data in a cold room, de-identifies the data, and re-uploads.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Identifiers will be stored separately from analysis data. Identifiers are shared from DHCS to RAND via a secure SFTP folder. RAND downloads the identifiable data in a cold room.

DISK STORAGE

State whether all disks with PID will be destroyed.

No disks with PID will be utilized in this project.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All computer access is protected through encryption and passwords and all RAND computers access a RAND secure server.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

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

All workstations have FIPS 140-2 compliant software, which was approved in our BAA with DHCS.

FIPS 140-2 COMPLIANCE: LAPTOPS

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

All laptops have FIPS 140-2 compliant software, which was approved in our BAA with DHCS.

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.

We are not using thumb drives, CD/DVD, or smartphones for any of this data.

SECURITY PATCHES

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

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

PASSWORD CONTROLS

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

All workstations and laptops and servers are password protected and connect through a RAND secure server.

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, RAND utilized sufficient system security controls, included automatic screen timeout, anti-virus protection, and a secure server.

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 (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2, as outlined and approved in our SOW and BAA with DHCS.

INTERNET ACCESSIBILITY

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

Identifiable information will be accessed in a cold room, which does not connect to the internet, and then de-identified before being uploaded to a RAND secure server.

DISPOSING OF PID

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

Yes, RAND staff will dispose of PID with sufficient, RAND approved deletion software.

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.

We will explain the project and procedures to all interview and survey participants, explain any potential risks and benefits, and give them an opportunity to ask questions and an opportunity to decline to participate. We will also provide RAND's IRB contact information, so they can contact our IRB with any further questions or concerns. We will obtain verbal consent to audio record interviews, and they can decline audio recording and still participate in 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.

CARE Act Petitioner Survey Consent.docx	Consent Form
CARE Act Respondent Survey Consent Script.docx	Consent Form
CARE Petitioner Interview Consent	Consent Form
CARE Respondent Interview Consent Form	Consent Form

Deleted Attachments: 6 (Most Recent: CARE Petitioner Interview Consent Script (1).docx on 01/04/2026 10:31 PM ET)

TRANSLATED DOCUMENTS

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

Survey Scales - Spanish.xlsx Consent Form

Deleted Attachments: 1 (Most Recent: Survey Scales - Spanish.xlsx on 01/04/2026 10:31 PM ET)

TRANSLATOR

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

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

Spanish Translator CV Translator Curriculum Vitae

Deleted Attachments: 3 (Most Recent: Spanish Translator CV on 01/04/2026 10:31 PM ET)

HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

Since DHCS has required a HIPAA Waiver from CPHS, please follow the steps below:
•For the question in the "Covered Entity" box (this section), select "Yes."
•Selecting "Yes" will prompt additional relevant sections.
•Under the "HIPAA Waiver" section, answer "Yes" to the question: "Are you requesting a waiver or alteration of HIPAA authorization?"
•This will generate the required questions for requesting a HIPAA Waiver from CPHS.
Note: Provide Variable Names
• When answering the HIPAA Waiver questions in this section, please provide a simple list of the variable names for which you are requesting approval. Only the names are needed—no descriptions or formatting. This list will be included in the final CPHS approval letter to specify the variables covered under the HIPAA waiver.
o Examples of variable names include:
—Date of birth
—Zip code
—Date of death

12/23/2025 • Sussan Atifeh • *Not* Internal

No

HEALTHCARE PROVISIONS

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

Yes

BILLING/ELIGIBILITY

If the study involves the provision of healthcare, will a health insurer or billing agency be contacted for billing or eligibility?

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

HIPAA WAIVER

Are you requesting a waiver or alteration of HIPAA authorization?

If you have already received a waiver/alteration from another IRB choose 'waiver/alteration approved by another IRB'. You do not need to apply for a waiver or alteration as the HIPAA waiver or alteration of authorization is only required from one IRB.

Yes

Provide a detailed description of the protected health information (including databases and variable names) to be utilized, and the HIPAA covered entity for which a waiver or alteration of authorization is required.
Protected health information will be included in all of the data variable lists we attached that DHCS will share with us. These databases include: the CARE Act Data Dictionary, CalOMS, DSH, HCAI, and Medi-Cal Claims Data. DHCS will serve as the HIPAA covered entity. The variables include: name, social security number, birthdate, Medi-cal client index number, phone number, address, zip code, county of residence, date of death (if applicable), hospitalizations, ED visits, race, ethnicity, veteran status, disability status, sexual orientation, medication, other health insurance status and insurance ID numbers where applicable, record ID for DSH admissions and discharges, beneficiary ID number, inpatient admission and discharge dates, primary diagnosis code, secondary diagnosis code, procedure codes, Medicare enrollment status, language, gender, sex, MEDS ID, any other diagnosis code, HCAI patient identifier

Provide a description of why the research cannot practicably be conducted without the waiver or alteration.
The research cannot practicable be conducted without the waiver because we need to link various datasets to fully understand, analyze, and evaluate the CARE Act respondents engagement with services, diagnoses, medication adherence, housing status, and health outcomes before and after engaging with the CARE Act process. Many respondents go in and out of care, interact with hospitals and EDs regularly, and these are outcomes that are being analyzed for the evaluation. We need to create a whole picture of each respondent's health journey and outcomes for a successful and robust evaluation of the CARE Act.

Provide a rationale for why the research could not practicably be conducted without access to and use of the protected health information.
We are legislatively mandated to conduct and independent evaluation of the CARE Act, and the legislation stipulates that "5986. (a) An independent, research-based entity shall be retained by the department to develop, in consultation with county behavioral health agencies, county CARE courts, racial justice experts, and other appropriate stakeholders, including providers and CARE court participants, an independent evaluation of the effectiveness of the CARE Act. The independent evaluation shall employ statistical research methodology and include a logic model, hypotheses, comparative or quasi-experimental analyses, and conclusions regarding the extent to which the CARE Act model is associated, correlated, and causally related with the performance of the outcome measures included in the annual reports. The independent evaluation shall include results from a survey conducted of program participants. The independent evaluation shall highlight racial, ethnic, and other demographic disparities, and include causal inference or descriptive analyses regarding the impact of the CARE Act on disparity reduction efforts."

Provide a detailed account of the plans and measures that will be in place to protect identifiers from improper use and disclosures.
Melissa Labriola, the PI of the project, will have responsibility for data safeguarding throughout the duration of the project. She will ensure the processes are shared with the team, and that the processes are implemented. A senior statistician will take responsibility for ensuring the quantitative team follows all data transmittal, storage, and destruction processes. Data files will be transferred from California Department of Health Care Services (DHCS), with whom we have a BAA signed via a secure SFTP server. The data will be transferred via a secure file transfer service, Winzip Enterprise, which is FIP compliant. Once encrypted via Winzip, DHCS will then share the file with RAND via Kiteworks. The designated quantitative team member(s) will download the data from Kiteworks and will immediately transport the data either to the Santa Monica or Washington D.C. cold room,

where they will then decrypt the data for analysis. Once in the cold room, data will be put into an analytic file, and the quantitative analysis team members will receive files with a scrambled personal identifier, not name or email, making the data de-identified.
1. Data will be stored on a secure, password-protected RAND server. Access to the specific directory will require a username and password and will be restricted to evaluation team members. Data may not be stored in any other location, including other machines, RAND-owned laptops/desktops/USB drives (with the exception noted above), extranet (e.g., external SharePoint site), home network, or unsecured private network.
2. Identifiable data will be stored on a cold room computer for the duration of the project.
3. Under no circumstances may these data be stored on the open web or reside outside of a RAND-owned resource.
4. Project staff will undergo training on project-specific data sensitivity and data safeguarding practices as required. Staff will annually review the inventory of sensitive data and the associated data safeguards.
Any inadvertent or intentional disclosure of private information to unauthorized parties must be reported to the RAND Human Subjects Protection Committee using the Adverse Event Reporting Form as well as to CPHS and will follow their adverse events reporting protocol.
All reports and publications will be reviewed by the Principal Investigators (PIs) to ensure adherence to publication standards. These standards are designed to ensure that tabular and graphical presentations of the data do not compromise the confidentiality of individuals.
RAND has a BAA in place with our funder, DHCS and will procure data securely through DHCS. If there are any discrepancies between the data safeguarding procedures outlined in the data sharing agreements and those specified in the data safeguarding procedures for highly sensitive data in the RAND matrices for data transfer, storage, and destruction, project staff will follow the more rigorous data safeguarding procedure.

Provide a detailed description of the plans to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law, include that rationale in your response.
Data will be destroyed at the end of the evaluation, or throughout the project if allowable. The end date for this project is March 31st, 2029, so the data will be destroyed on or before that date.

In all cases, data transfer, storage, and disposal will be accomplished in accordance with the guidelines on RAND’s data security standards. Data Destruction

Macintosh:The macOS + Apple File System's built-in functionality of auto-trimming SSD free space are the industry standard for secure file deletion.
In these cases, you just have to delete the file, empty the trash, and restart the machine.
Explanation
On a Mac SSD formatted with APFS, the free space on the SSD will be automatically trimmed the next time you restart the Mac. You can verify this via Terminal by running the following command (customizing for the date range desired):

Windows:For Windows laptops and servers, using SDelete is the industry standard for securely deleting files. Sdelete is a secure deletion utility created by Microsoft. This is used for not only deleting a file, but also overwriting its previous location on the drive with 0’s to prevent recovery. It should go without saying, but because this tool is intended to destroy files irrecoverably, be very careful when selecting files or folders for deletion.

This procedure only demonstrates how to purge the file from your local computer. If the files were backed up via Druva, OneDrive, or Veeam, they will need purged from those systems with the assistance of Information Services.

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

CARE Act Eval Budget SOW and BAA Project Budget

Deleted Attachments: 1 (Most Recent: CARE Act Eval Budget SOW and BAA on 01/04/2026 10:31 PM ET)

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Cover Letter Cover Letter

Deleted Attachments: 1 (Most Recent: Cover Letter on 01/04/2026 10:31 PM ET)

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 Services: CARE Act Data Dictionary
Department of Health Care Services: MID/DSS Claims
Department of Health Care Services: MEDS_MISDSS Claims
Department of Health Care Services: Cal OMS Data

PI Signature for Coordinator Submission (Initial)
- Submitted 12/24/2025 11:40 AM ET by Melissa Labriola, PhD

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, December 24, 2025 11:40:14 AM ET by Melissa Labriola, PhD

Responsible Official Signature
- Submitted 12/17/2025 2:05 PM ET by Peter Hussey, PhD

Responsible Official Signature

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

Yes, ready for submission to IRB.

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

Signed Wednesday, December 17, 2025 2:05:54 PM ET by Peter Hussey, PhD

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

Notify IRB for Pre-Screening
- Submitted 12/24/2025 3:31 PM ET by Sussan Atifeh

Internal IRB Screening

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

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

Yes

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

CPHS

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

Full Board Minimal Risk

Please provide a rationale for your level of review preliminary determination
New Project with human subjects' contacts

Choose the CPHS Chair
Larry Dickey, MD, MPH, MSW

Select the vice chair of the committee
Larry Dickey, MD, MPH, MSW

Assign to Cycle

February

Assign to cycle year
2026

Load into IRBManager (Initial Submission)
- Submitted 12/24/2025 3:31 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 01/20/2026 11:57 AM ET by Sussan Atifeh

Full Board Set Up

Project number

2025-201

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

Confirmation of level of review

Full Board Minimal Risk

Provide the rationale for the level of review determination
This project has human subjects' contacts components and should be discussed in the CPHS February 6th, 2026, Full Board meeting.

Assign SME to study

Maria Ventura, PhD

Enter the meeting date for this project

02/06/2026

SME Review

SME review

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

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

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

No answer provided.

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