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 09/04/2025 12:55 PM ET by Danielle Oleskiewicz, PhD

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

October 2025 cycle.

----------New HSC Project----------

Is it a Program Evaluation/Improvement??????????? To be clarified by the Chairs.

09/05/2025 • Sussan Atifeh • Internal

Researchers from the California Department of Aging (CDA) have submitted this project application to request approval for a project with human subjects' contacts components. The study is aimed to evaluate how well the Cal Community Connect program is working over a two-year period. This initiative supports the state's No Wrong Door (NWD) system, which helps older adults, individuals with disabilities, and caregivers access long-term services and supports (LTSS) more easily. The project will pilot trained Community Health Workers (CHWs)—referred to as NWD navigators—within Area Agencies on Aging (AAAs) in San Diego, Sacramento (Yuba/Sutter counties), and Sonoma. CDA's research team will evaluate the program over two years by tracking outreach efforts, navigator training, participant engagement, and service utilization. Surveys will be administered at intake and six months later to assess changes in quality of life, caregiver burden, and healthcare use.
Participants include older adults, individuals with disabilities, and caregivers who seek services through the program.

Initial contact happens when participants engage with trained No Wrong Door (NWD) navigators at local Area Agencies on Aging (AAAs).

Surveys are administered at two points: once at intake (before services are provided), and again six months later. These surveys are sent electronically via SurveyMonkey.

Survey content includes sociodemographic questions, and questions about service access, hospital visits, emergency room use, quality of life, and caregiver stress.

Project site:
California Department of Aging---A DSL from CDA is included.

No Request for State Data California Department of Aging (CDA)---A LOS from CDA is attached.

Funding: federally funded by ACL Administration for Community Living

Non-English translation required: Translated documents are not attached---No Translator Certificate yet

09/05/2025 • Sussan Atifeh • 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.

Danielle Oleskiewicz, PhD

Email: danielle.oleskiewicz@aging.ca.gov **Business:** (916) 269-2101

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

California Department of Aging

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

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

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

California

Attach a copy of the PI's Curriculum Vitae.

DOleskiewicz_CV_3-13.pdf 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.

BRIAN CARTER

Email: brian.carter@aging.ca.gov **Business:** (916) 928-4669

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

Brian T Carter REsume 12.2024.pdf 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.

Danielle Oleskiewicz, PhD

Email: danielle.oleskiewicz@aging.ca.gov **Business:** (916) 269-2101

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.*

Ross Lallian, M.S.

Email: ross.lallian@aging.ca.gov **Business:** (916) 326-3713

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.

Ross Lallian, M.S.
Email: ross.lallian@aging.ca.gov **Business:** (916) 326-3713

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

False

Project Information

SUBMITTER

Application completed by:

Danielle Oleskiewicz, PhD
Email: danielle.oleskiewicz@aging.ca.gov **Business:** (916) 269-2101

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).

Cal Community Connect: Advancing California's Aging and Disability No Wrong Door System

PROJECT SITE

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

California Department of Aging

STUDY PROCEDURES

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

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.

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

Minimal Risk
Non-English translation required
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
Economically or Educationally Disadvantaged Persons

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Federally funded

Enter name of federally-funded source.
Administration for Community Living

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

10/03/2025

ANTICIPATED PROJECT END DATE

06/01/2027

Project Details

PURPOSE

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

Californians are struggling to find the information they need to make informed choices about long-term service and support (LTSS) options. In fact, in California's 2023 Consumer Assessment Survey of Older Adults, 72% of the 17,000 respondents reported having problems with knowing what services were available in their local community (CDA, 2023). Without a known or centralized location for information, people cannot access the services they need when they need them—increasing the likelihood of unnecessary hospitalization or institutionalization.

Cal Community Connect will advance California's No Wrong Door (NWD) system by streamlining access to LTSS through trained and certified Community Health Workers (CHW) serving as NWD navigators (herein referred to as NWD navigators). California will pilot a NWD navigator role within the Area Agencies on Aging (AAA) of San Diego, Sacramento (this multi-county AAA will focus on Yuba and Sutter counties), and Sonoma to support older adults, people with disabilities and caregivers in their LTSS navigation journey – while building the business case for sustainability using Medi-Cal and/or Medicare funding streams.

The goal of this research project is to conduct an evaluation of the Cal Community Connect program. Therefore, this evaluation seeks to answer the following research questions:

1. Does the Cal Community Connect program increase awareness and access to available services and support for program participants?
2. Does the Cal Community Connect program reduce caregiver burden for those who provide care to program participants?
3. Does the Cal Community Connect program reduce the number of emergency room visits, hospitalizations, and institutional placement among older adults and individuals with disabilities who are experiencing care transitions (e.g., hospital-to-home)?
4. Does the Cal Community Connect Program result in improvements in quality of life and confidence in maintaining their desired living situation?

As a result of this evaluation and deployment of Cal Community Connect, there will be a creation of a communications toolkit, featuring information on implementing the program, opportunities to do so, best practices, and FAQs outlining lessons learned. This will also include models for billing Medi-Cal and Medicare for NWD services provided by CHWs, communication strategies, transportation services, and program costs.

MAJOR RESEARCH QUESTION

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

Does the implementation of a No Wrong Door system (Cal Community Connect) in California improve older adults', people with disabilities', and their caregivers' awareness of services, access to services, caregiver burden, care transitions, and quality of life?

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 California Department of Aging will conduct an evaluation utilizing its research team to track the implementation of Cal Community Connect and its predicted outcomes. Over the course of two years, CDA will collect and maintain a dataset using an excel file template on One Drive, which will include a measure on outreach efforts (i.e., materials distributed and event attendance), the number of newly trained and certified NWD navigators, and the number of Cal Community Connect participants and services utilized by these participants. No Wrong Door (NWD) navigators at each partner site will track which services are utilized, number of referrals made, and follow-up interactions. As NWD navigators interact with program participants, they will use the excel template to track these outputs. The program will be considered successfully implemented if each AAA trains at least one NWD navigator and if the three sites outreach to at-least 7,000 individuals and serve at least 335 participants with connections to at least two services. Quarterly evaluations will be conducted to assess progress towards the proposed goals and allow CDA and its partners to identify and document any barriers to meeting goals.

A survey will be administered both at intake and approximately six months after intake. There will be two versions of the same survey, one for older adults and people with disabilities which will include the question assessing subjective ability to navigate services, the number of hospitalizations in the past six months, the number of emergency room visits in the past six months, institutional care status, confidence in maintaining living in their community of choice, and self-reported quality of life. The second survey will be tailored for caregivers and will include an additional module with the Zarit Burden Interview. All surveys will be administered electronically using Survey Monkey. The baseline survey will be sent to participants when they first seek services, before any services are rendered by the NWD Navigator. The second survey will be administered post navigation services are rendered (approximately six months). This survey will assess whether participants report fewer hospitalizations, fewer emergency room visits, are community-dwelling, experience improvements in quality of life, and if caregivers experience a decrease in caregiver burden post navigation services. CDA's staff researchers will conduct analyses to determine if these outcomes differ significantly across the two time-points.

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.

Cal Community Connect_C_Baseline_8-27.docx	Questionnaires
Cal Community Connect_C_T2_8-27.docx	Questionnaires
Cal Community Connect_P_Baseline_8-27.docx	Questionnaires

Cal Community Connect_P_T2_8-27.docx	Questionnaires

Deleted Attachments: 4 (Most Recent: Cal Community Connect_P_T2_8-27.docx on 09/04/2025 11:39 AM ET)

RECORDING

Will audio or video recording occur?

No

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.

CDA: Department of Aging

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.

The sample will consist of older adults (ages 60 years or older), people with disabilities, and their caregivers who seek services and support from one of three partner sites (San Diego County Area Agency on Aging, Agency on Aging Area 4, and Sonoma County Area Agency on Aging). Participants will be diverse in terms of race and ethnicity, and gender will vary. The target sample size is 335 participants.

RATIONALE

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

Older adults and people with disabilities have a pronounced need for long-term services and support (LTSS), in part due to their increased likelihood of developing physical, mental, cognitive, or chronic health conditions. Those who provide care for older adults and people with disabilities often experience adverse impacts to their mental and physical health because of their caregiving responsibilities, which often include intense, around-the-clock care. Older adults, people with disabilities, and their caregivers face obstacles when seeking available services, which can be both overwhelming and time consuming. Therefore, older adults, people with disabilities, and their caregivers are the target population for this evaluation.

RECRUITMENT DETAILS

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

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

Participants will be contacted through flyers, social media postings, postings on the Area Agency on Aging's (AAA) website, 1-800 number called when potential participants seek services, and through targeted outreach to partners of the AAAs including senior centers, non-profits, low-income senior housing sites, key community meetings, and faith-based organizations. Employees of the AAAs will be the ones posting flyers, answering 1-800 numbers, conducting outreach, posting on social media, and facilitating recruitment.

Attach copies of all recruitment materials.

Cal Community Connect Flyer Template.docx Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.
Participants must be adults 60 years or older, an adult with a disability, or a caregiver of adults 60 years or older or an adult with a disability. Participants will be screened prior to enrollment in the program and the study. Should participants not be eligible or decide not to join the program, their information will not be entered into the excel sheet nor will they be sent a survey where information would be collected. None of their data or information will be retained.

COMPENSATION

Will subjects be compensated for participating in the study?

No

STUDY DURATION

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

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

This is a two-year evaluation. Participants will be surveyed before the intervention and after the intervention, which is approximately six months. Total approximate time commitment for participants is 1 hour for survey completion over the course of 6 months.

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.

Risks for participants will be minimal. A loss of data security and of confidentiality is minimal, as all data will be kept on secure servers and any computers housing data will remain either with the primary user or locked away in a secure area. There is no physical, economic, or social risks, however, some of the questions in the survey pertaining to caregiver burden, quality of life, and housing may be upsetting.

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.

No services will be 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.

There are no less risky methods for this evaluation.

BENEFITS

Describe the benefits, if any, to the subjects or to society that will be realized as a result of this project. Discuss the benefits that may accrue directly to the subjects as well as to society. If there is no direct benefit anticipated for the subjects, state that clearly.

Participants will not benefit directly from this research. Society at large will benefit from the findings from this evaluation, as it will inform policy recommendations and future interventions that may be implemented statewide.

JUSTIFICATION OF RISKS

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

This study has minimal risks, none of which extend outside of the normal risks associated with participating in survey research. The minimal risks are reasonable given that the benefits to participants and society may include further evidence for implementing an intervention aimed at helping older adults and people with disabilities access the services they need.

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
Internet Protocol (IP) 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 research staff who will have access to PID will be trained using the OHRP Human Research Protection Training offered through the U.S. Department of Health and Human Services. All research staff will be required to sign a confidentiality statement related to general use, security, and privacy.

STAFF VETTING PROCEDURES

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

All the research staff will undergo the State of California's vetting procedures, which include thorough reference checks.

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.

CDA Letter of Support.pdf Department Letter of Support

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

Explain how you will ensure that data will not be reused or provided to any unauthorized person or entity.

Unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS.

Researchers have committed that data will not be reused or provided to any unauthorized entity.

CONFIDENTIALITY OF PUBLISHED DATA

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

All data reporting will be confidential. No data will be presented or published that could possibly be used to identify an individual subject.

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?

The data will be used to evaluate a specific intervention from a two-year grant. We are only collecting the necessary data to conduct our evaluation and the necessary sociodemographic information to assess differential attrition. We have not requested more than the minimum necessary data to perform this research.

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, data will be limited only to those with a need to know for purposes of implementing or evaluating research.

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.

CDA follows the Data De-Identification Guidelines (DDG), which protects the identity of individual subjects when small cells or numbers are involved in the research project.

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*

CDA - Data Security Letter for the IRB application.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.
Names, emails, birth dates, and phone numbers will be removed from analysis data and an identification number will be assigned to each participant. Ages over 89 will be recoded to 90+.

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.

PID in paper form will be shredded through cross shredding or pulverizing.

FAXING

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

PID will not be faxed.

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.

PID will not be mailed.

ELECTRONIC STORAGE

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

CDA staff laptops and portable electronic storage media containing data with PID will never be left unattended in cars or other unsecured 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.

CDA offices are locked and badge operated. There is 24-hour monitored alarm service.

SERVER SECURITY

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

All servers containing encrypted PID are housed in a secure room with controlled access procedures.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Identifiers will be stored separately from analysis data. Participants will be assigned an Identification Number, which will be used to link Wave 1 and Wave 2 data. Consent forms and PIDs will be stored separately.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID will be destroyed.

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 using encryption, passwords, and other protections.

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 that contain PID have full disc encryption that uses FIPS 140-2 compliant software.

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 that contain PID have full disc encryption that uses FIPS 140-2 compliant software.

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.

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

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.

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

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.

Sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, 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 (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.

INTERNET ACCESSIBILITY

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

PID in an 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.

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

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.

Screened participants who are sent a baseline survey will be given a digital consent form before answering any of the survey questions. If participants consent to the evaluation, a digital signature will be recorded and stored separately from the survey data. On the consent form, participants will also be linked to a copy of the Bill of Rights.

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.

Cal Community Connect_Informed Consent Form.docx	Consent Form
CPHSBillofRightsMed.pdf	Consent Form

TRANSLATED DOCUMENTS

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

Spanish Translation Note	Consent Form

TRANSLATOR

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

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

Cal Community Connect_Translation Note.docx	Translator Curriculum Vitae

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

Cal Community Connect Budget Narrative Justification.pdf Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Cal Community Connect_CPHS Cover Letter.pdf Cover Letter

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

Signed Thursday, September 4, 2025 12:50:23 PM ET by Danielle Oleskiewicz, PhD

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

Responsible Official Signature
- Submitted 09/05/2025 1:47 PM ET by Ross Lallian, M.S.

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, September 5, 2025 1:47:12 PM ET by Ross Lallian, M.S.

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 09/05/2025 6:30 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
Involved with Human subjects' contacts.

Choose the CPHS Chair
Catherine Hess, PhD

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

Assign to Cycle

October

Assign to cycle year
2025

Load into IRBManager (Initial Submission)
- Submitted 09/05/2025 6:30 PM ET by The System

Chair Review and Full Board Set-Up

Full Board Set Up

Project number

2025-136

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

No answer provided.

Provide the rationale for the level of review determination
No answer provided.