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 06/01/2026 1:33 PM ET by Lia Scott, PhD, MPH

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

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.

Lia Scott, PhD, MPH

Email: liascott@berkeley.edu **Business:** (404) 507-2916

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

University of California, Berkeley

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

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.

Scott CV 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.

No answer provided.

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.

Lia Scott, PhD, MPH

Email: liascott@berkeley.edu **Business:** (404) 507-2916

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.*

Adrienne Tanner

Email: a.tanner@berkeley.edu **Business:** (510) 642-7461

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.

Arshya Gurbani, PhD

Email: arshya.gurbani@berkeley.edu **Business:** (510) 642-6000

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

False

Project Information

SUBMITTER

Application completed by:

Lia Scott, PhD, MPH

Email: liascott@berkeley.edu **Business:** (404) 507-2916

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).

Building a Geographically Diverse Cohort to Examine the Multilevel Effect of Racism on Breast Cancer

PROJECT SITE

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

University of California, Berkeley

STUDY PROCEDURES

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

Data Registry
Recruitment-Participant
Surveillance Data

TYPE OF RESEARCH REQUEST

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

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

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

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

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

Common rule/Human subjects

PROJECT TYPE DETAILS

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

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

Minimal Risk
Consent form

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.

Economically or Educationally Disadvantaged Persons

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
University funded

EXPEDITED REVIEW CONSIDERATION

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

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

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

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

Not applicable

ANTICIPATED PROJECT START DATE

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

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

06/05/2026

ANTICIPATED PROJECT END DATE

06/01/2028

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.

The pilot project will build a cohort of cancer survivors from diverse geographic areas to better measure interpersonal and structural experiences of racism, measure associations with clinicopathologic characteristics at diagnosis and follow them through their treatment, survivorship and other outcomes. Black women are more than twice as likely to be diagnosed with triple-negative breast cancer than white women, more likely to be diagnosed at a later stage, and more likely to be diagnosed before age 40—earlier than screening recommendations. There is a consensus that age and race play significant roles in the diagnosis of breast cancer, yet with the knowledge we have, disparities persist. If we continue to inadequately address the role of racism rather than race in disparities, we will limit ourselves to the misconception that race reflects inevitable biological differences rather than recognizing that race is a social construct that categorizes people in a hierarchy of privilege.

This proposal aims to recruit a diverse cancer epidemiology cohort of women residing in the Bay Area diagnosed with first primary malignant neoplasm of the breast between 2019 and 2024, followed through 2029, with the long-term goal of delineating the multi-level impact of racism on their diagnosis and subsequent outcomes. This group will be pooled with a cohort from metropolitan Atlanta and will serve as a foundation for studies to come focused on quantifying the effect of structural racism at the neighborhood level, interpersonal racism and identify any cross-level interactions on clinicopathologic characteristics at diagnosis and 5-year outcomes. This specific proposal will focus on recruitment of a post-doctoral fellow for the study team, Greater Bay Area survivor recruitment and geocoding and linkage of secondary data.

Bay Area cancer patients aged 18 to 64 years diagnosed with a first primary malignant neoplasm of the breast (ICD-O-3=C50) between 2019 and 2024, will be identified in the Greater Bay Area Cancer Registry. Geographic coverage includes Alameda, Contra Costa, Marin, San Francisco, San Mateo, Monterey, San Benito, Santa Clara, and Santa Cruz counties in the Bay Area of California. We expect that experiences of interpersonal and structural racism will be associated with early-onset, later stage diagnosis, increased likelihood of triple-negative subtype, and poorer clinical characteristics.

The project will be conducted at University of California, Berkeley.

MAJOR RESEARCH QUESTION

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

What is the effect of multiple levels of structural inequity and experiences of racism on early-onset and etiologic heterogeneity among women with first diagnosis of invasive breast cancer and their subsequent outcomes?

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

Aim 1. Identify and recruit breast cancer survivors diagnosed between 2019 and 2024, geocode based on residence at diagnosis and birthplace and link to external structural racism measures. Bay Area cancer patients aged 18 to 64 years diagnosed with a first primary malignant neoplasm of the breast (ICD-O-3= C50.0–C50.9) between 2019 and 2024, will be identified in the Greater Bay Area Cancer Registries. Institutional IRB approval will be obtained, and a case listing application will be submitted to the Greater Bay Area Cancer Registry. In our application, we will request patient contact. In accordance with registry guidelines, we will initiate contact through writing. A letter explaining our study will be mailed with a link to the eConsent and survey in REDCap(attached). The letter will also contain details on how to opt out of our or any future studies. Only the PI and post-doctoral fellow will have access to the study email and phone number. Additionally, only the PI and post-doctoral fellow will have access to the contact information provided by the registry that links PII to cancer data.

Data Linkage: Clinicopathologic characteristics will be noted and coded at diagnosis including diagnostic year, race/ethnicity, age, stage, tumor marker expression, tumor size, histological grade, initial treatment modality, primary payment/insurance status, birthplace and residence at diagnosis. Participants will be geocoded separately based on birthplace and residence at diagnosis. The case listing file will be merged with a secondary data set containing multiple measures of structural racism and the social environment. The case listing will contain the census tract in which the patients resided at diagnosis. Using the 11-digit FIPS identifier, we will link the individual data to the publicly available secondary dataset we will create.

A secondary dataset will be developed to include measures at the census tract level. Variables included will be Census-derived measures of poverty, education, and employment from the American Community Survey 2019-2024 5-year estimates. This data is publicly available and will be obtained using R statistical software. Using the ndi package from R, we will calculate the aspatial Index of Concentration at the Extremes, Local Exposure and Isolation, Location Quotient, and Messer and Powell-Wiley Neighborhood Deprivation Indices and spatial measures of Anthropolos' racial isolation and Bravo's educational isolation. Finally, we will calculate three Massey and Denton measures of residential segregation measuring evenness – dissimilarity – and exposure – interaction and isolation. All of these variables are derived from publicly available census data stated above.

Expected Outcomes: We expect to have a complete case listing from the Greater Bay Area Cancer Registries from which we will develop a descriptive analysis of the cohort. A census-tract level external dataset will be

completed and linked to the case listing file using census tract geographic identifiers. We expect to identify approximately 14,000 cases over the 5-year period with 800 cases among Black women, 8,500 cases among white women, 4,650 cases among Asian/Pacific Islander women with 3,035 cases classified as Hispanic. Using registry data, we anticipate that 1,400 cases (10%) will be classified as TNBC or early-onset, independently. With these sample sizes, we have sufficient statistical power (0.99) to detect a mean difference in outcomes between Black and White women corresponding to Cohen's d of 0.2. Power was calculated in R pwr package using two-sample t-tests with common error variance and an alpha=0.01.

Please upload here any tables or charts related to your study procedures and any materials (such as surveys or interview questions) that will be presented to participants.

Consent Form - UCOP Pilot - lower RL.pdf	Consent Form
Patient Contact Letter	Recruitment Materials
Study Brochure	Recruitment Materials

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.

Not applicable

STATE DEPARTMENT DATA/SPECIMENS

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

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	Greater Bay Area Cancer Registry

Study Population

POPULATION DESCRIPTION

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

We expect to identify approximately 14,000 cases over the 5-year period with 800 cases among Black women, 8,500 cases among white women, and 4,650 cases among Asian/Pacific Islander women. The initial case listing will include females, all races/ethnicities, with 3,305 cases expected to be Hispanic ethnicity. Language and literacy will not be assessed in the initial case listing.

DATABASE DETAILS

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

List the variables being requested, including a brief description of each variable.
Justify the need for each variable and for the quantity of data being requested.
You may also attach a list of variables on the next question.

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

Greater Bay Area Cancer Registry from 2019 - 2024 or most recent data available, whichever is later. Variables requested from GBACR are attached. Patient contact will be requested and eligible patients may be involved in future studies.

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.

GBACR Data.pdf List of Variables

RATIONALE

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

This study aims to build a cohort of geographically, racially and ethnically diverse cancer survivors. Inclusion of all female breast cancer cases from 2019 forward will ensure these subgroups are large enough to measure the differences in the role of racism on clinicopathologic characteristics between these groups.

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.

Subjects will be identified through the cancer registry. Eligible patients will be provided by the registry and contacted via mail using contact information received from the registry. In the mailing, we will include a patient contact letter, the CCR brochure and a study brochure.

Attach copies of all recruitment materials.

CCR Brochure	Recruitment Materials
Patient Contact Letter	Recruitment Materials
Study Brochure	Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

No

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
Participants will be compensated $60 for their time. It is anticipated that the survey will take a minimum of 60 minutes to complete. The amount will be prorated according to completion of survey beginning at 50% completion. If a participant completes 50% or less of the survey, then they will receive $30.

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 multi-year study, with initial data collection and cleaning occurring in the first year. We expect data collection, pooling and cleaning to take one year after IRB approval.

Risks and Benefits

RISK DESCRIPTION

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

The risk of confidentiality breach is minimal. Cancer registry data will be stored in the SRDC.
Addresses for the patient contact listing will be kept separately from registry and subsequent survey data.

Should a breach occur the potential harm to participants is minimal, there may be larger social implications such as loss of confidence in the surveillance system. There are no other anticipated risks or discomforts associated with this case recruitment.

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 medical 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.

The study is being conducted with minimal risk. Less risky methods would include contact via email or phone, rather than writing to avoid breach during mailing, however this is not possible given CCR requirements.

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.

The subjects will not benefit directly from study procedures. This study will allow us to learn more about the role of racism on breast cancer diagnosis and subsequent outcomes and we hope that this information will help in the future treatment and prevention of individuals with breast cancer.

JUSTIFICATION OF RISKS

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

Risks are minimal to participants and thus reasonable. While there are no direct benefits to participants, the greater benefit to society outweigh the minimal risks.

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)

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 have completed CITI Group 1 and 2 Courses and the Health Privacy (HIPAA) course

STAFF VETTING PROCEDURES

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

Staff completed a background check in order to be hired at UC Berkeley.

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.

GBACR Letter of Support Department Letter of Support

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

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

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

Data will be stored in the P4 Secure Research Data and Compute platform at UC Berkeley. All data will be encrypted and password protected. Only the PI and post-doctoral fellow will have access to the data on this platform.

CONFIDENTIALITY OF PUBLISHED DATA

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

Any information published could not be used to identify an individual subject. No data will be published publicly, only results from subsequent analyses. Data suppression and aggregation for small cell counts (<16) will be used in any publications

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 study requests the most recent 5 years of data from the cancer registry. Variables requested include clinically relevant pathologic characteristics of tumors. We will request contact information/patient contact in order to establish eligibility for a pilot survey.

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 the PI and the post-doctoral fellow

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.

Data suppression and aggregation for small cell counts (<16) will be used in any publications.

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.
Secondary dataset attached. The secondary data is publicly available and will be linked to individual data via geographic identifiers.

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.

UCOP - Secondary Data.pdf Other Documents

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*

2026-04-15-CPHS Data Security Letter - CISO Signed - Lia Scott.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.

The key will be stored on the SRDC in a separate file space from the data. Addresses for patients will be stored separately from cancer data. Once patients are consented they will be assigned a random ID and all other identifiable information such as name and contact information will be removed the analytic file.

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 will be received electronically. Any PID in paper form will be destroyed using cross cut shredding

FAXING

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

There will be no faxes involved in this study.

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.

There will be no mailings of PID

ELECTRONIC STORAGE

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

PID will be stored in electronic form via the Berkeley Secure Research Data and Compute Platform. The Secure Research Data and Compute (SRDC) Platform is a secure computing environment developed for researchers working with highly sensitive (P4) data. The SRDC includes high performance computing (HPC), computing on virtual machines (VMs) with Linux and Windows servers, and protected storage for both options.
No data will be stored directly on physical or portable electronic media.

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.

Facilities that hold Berkeley-controlled workstations and laptops have controlled access procedures for the building and the floor. While there is no physical data storage expected, workstations to access the data are protected.
An encrypted and password-protected case listing is provided by the GBACR. Once received, the case listing will be stored in the SRDC platform with P4 security. If the GBACR sends a physical copy of the data, the storage device will be kept in a locked filing cabinet, in the PIs locked office on UCB campus, after data upload to the SRDC.

SERVER SECURITY

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

All data will be stored the SRDC virtual computing platform.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

The key will be stored on the SRDC in a separate file space from the data. Addresses for patients will be stored separately from cancer data. Once patients are consented they will be assigned a random ID and all other identifiable information such as name and contact information will be removed the analytic file.

DISK STORAGE

State whether all disks with PID will be destroyed.

If any disks are received with PID, they 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 through encryption and passwords. Devices accessing the SRDC are fully encrypted with BitLocker. Devices will be stored on campus in locked cabinets, primarily. The SRDC is accessible via a secure gateway with multi-factor authentication, via an individually assigned password.

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 devices that will access the PID have full disc encryption via BitLocker

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 devices that will access the PID have full disc encryption via BitLocker

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.

PID will not be on removable media devices, unless the registry delivers that data on that format. All devices that will access the PID have full disc encryption via BitLocker.

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.

Yes, all devices 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.

Yes. All UCB passphrase's must:

Be at least 12 characters long (maximum 255) and may include spaces
Contain at least three of the four following character groups:
Uppercase letters (A through Z)
Lowercase letters (a through z)
Numbers (0 through 9) or
Symbols/special characters (!, $, #, or %, etc.)
Your passphrase must NOT:

Contain your first name, middle, or last name(s)
Contain your CalNet ID
Contain leading or trailing spaces

ELECTRONIC SECURITY CONTROLS

Indicate if sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews.

Yes, sufficient system security controls are in place for automatic screen timeout, 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.

Yes, any transmission of electronic PID will be encrypted with BitLocker

INTERNET ACCESSIBILITY

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

PID will not 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.

Secure wiping of electronic PID will occur in disposal.

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.

In accordance with registry guidelines, we will initiate contact through writing. A letter explaining our study will be mailed with a link to the eConsent in REDCap. The letter will also contain details on how to opt out of our or any future studies. The consent form will be converted to eConsent in REDCap

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.

Consent Form - UCOP Pilot - lower RL.pdf Consent Form

HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

BudgetJustification_UCOP CRCC_032125.pdf Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

IRB 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 Monday, June 1, 2026 1:32:18 PM ET by Lia Scott, PhD, MPH

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.

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

California Department of Public Health: Greater Bay Area Cancer Registry

Responsible Official Signature
- Submitted 04/17/2026 7:21 PM ET by Adrienne Tanner

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, April 17, 2026 7:21:03 PM ET by Adrienne Tanner

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

Notify IRB for Pre-Screening
- Submitted 05/20/2026 7:02 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
According to researchers, this project uses state data to contact subjects.

Choose the CPHS Chair
Catherine Hess, PhD

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

Assign to Cycle

June

Assign to cycle year
2026

Load into IRBManager (Initial Submission)
- Submitted 06/01/2026 1:34 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 05/20/2026 7:59 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2026-087

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
According to the Chairs, this project should be discussed in the June 5th Full Board meeting.

Assign SME to study

Maria Ventura, PhD

Enter the meeting date for this project

06/05/2026

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.

Yes

Enter any additional comments that you have for the researcher (in addition to your notes) here.
Please reduce the reading level for the consent form (currently at 12th grade, needs to be at 8th grade max). Also please see questions about inclusion of diverse sample including Hispanic women, and brochure form contact information.

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.