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 12:43 PM ET by Rachel Vogel, PhD

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

October 2025 cycle.

_____HSC Project_____

Requesting data from CCR—A LOS from CCR is attached.
Main site of the Project: University of Minnesota—A DSL from UMN is attached.

••••••••••••Non-English Translations are included in this application and should be reviewed and approved by Dr. Ruiz after the English versions are finalized and approved by the SME of this project or by the Full Board.

••••••••••••

09/02/2025 • Sussan Atifeh • Internal

Researchers from the University of Minnesota have submitted this application to request approval for a project that is aimed to comprehensively describe the unmet needs and quality of life of ovarian cancer survivors. They plan to contact and recruit individuals by mail in the California Cancer Registry who have been diagnosed with ovarian, fallopian tube or primary peritoneal cancers between 2014 and 2024 to participate in a one-time survey study with a potential for a follow-up interview with research study staff.
Researchers aim to document the ongoing physical, psychosocial, and supportive care needs of ovarian cancer survivors in California. Using the CCR data, the research team will recruit approximately 5,000 survivors diagnosed between 20214-2025, with targeted oversampling of underrepresented groups such as American Indian/Alaska Native, Non-Hispanic Black, Hispanic, rural, and newly diagnosed individuals. About 2,000 participants are expected to complete a one-time survey on their experiences, barriers to care, and unmet

needs. Up to four mailings (initial letter, thank you card, reminder, and final letter) will be used to maximize response. Participants who complete the survey may also enter a drawing for a $200 gift card.
Up to 40 survey participants will be invited to complete 30–45-minute follow-up interviews by phone or zoom, with $50 compensation to provide deeper insights into the survey findings. Interviews will be recorded, transcribed, and analyzed using mixed methods.
Per researchers, all participants will be assigned a study ID, and this ID will be linked to all data. The contact information provided from the CCR will be stored separately. The link between the study ID and participant data will be destroyed after 10 years.

• Project Title: "Understanding the Experience of Ovarian Cancer – Life After Diagnosis (UNTOLD) Study."

• Funding: Federally funded by Centers for Disease Control and Prevention (CDC).

• Data-Source Department(s): California Cancer Registry (CCR). A LOS from CCR is attached.

• Main site of the Project: University of Minnesota. A DSL from UMN is attached.

• Spanish Translations: A Translator Certificate from the BURG Translations, Inc. is attached.

• Linkage: All participants will be assigned a study ID, and this ID will be linked to all data. The contact information provided from the CCR will be stored separately. The link between the study ID and participant data will be destroyed after 10 years

• End-Product: The expected outcome of this study is a comprehensive description of survivorship experiences among ovarian cancer survivors which will be shared through manuscripts and presentations.

• This project has been approved by the University of

Minnesota Institutional Review Board (STUDY00023547, 02/04/2025).

••• They provide informed consent form to the subjects; however, they requested approval for not documenting the consent form.

09/02/2025 • Sussan Atifeh • Internal

Dear Researcher: Thanks for addressing the majority of the comments. Please check page 3 of this application and address the new comment in the "STATE DEPARTMENT DATA/SPECIMENS" section and resubmit.

Thanks.

09/02/2025 • Sussan Atifeh • *Not* Internal

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

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Rachel Vogel, PhD

Email: isak0023@umn.edu **Business:** (612) 624-6928

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

University of Minnesota

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

Minneapolis

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

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

Minnesota

Attach a copy of the PI's Curriculum Vitae.

Vogel_CV_Nov2024.docx PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

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

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

Helen Parsons, PhD MPH

Email: pars0100@umn.edu **Business:** (612) 625-0404

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

Parsons UMN CV_11_2024 CCR.docx Co-PI Curriculum Vitae

ADMINISTRATIVE CONTACT

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

Rachel Vogel, PhD

Email: isak0023@umn.edu **Business:** (612) 624-6928

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.*

Colleen Rivard, MD

Email: clrivard@umn.edu **Business:** (612) 626-3111

OTHER RESEARCH STAFF

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

Please ensure you have listed in this section "all" research staff who interact directly with participants (as in interviews or focus groups) or who will have access to the data.

09/02/2025 • Sussan Atifeh • *Not* Internal • Resolved

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.

Katherine Brown, BS
Email: brow3238@umn.edu **Business:** (612) 624-9904

Patricia Jewett, PhD
Email: jewet050@umn.edu **Business:** (612) 624-9904

Emma Kelly, BS
Email: kell3139@umn.edu **Business:** (612) 624-9904

Allison Dona, BA, BS
Email: dona0296@umn.edu **Business:** (612) 624-9904

Sarah Boyle, MD
Email: david441@umn.edu **Business:** (612) 624-9904

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

False

Project Information

SUBMITTER

Application completed by:

Rachel Vogel, PhD
Email: isak0023@umn.edu **Business:** (612) 624-6928

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).

Understanding The Experience of Ovarian Cancer – Life After Diagnosis (UNTOLD) Study

PROJECT SITE

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

University of Minnesota

STUDY PROCEDURES

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

Data Registry
Interviews
Recruitment-Participant
Surveys

TYPE OF RESEARCH REQUEST

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

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

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

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

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

Common rule/Human subjects

PROJECT TYPE DETAILS

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

You mentioned, "We request the waiver of documentation of consent."

Does it mean that you provide informed consent to the participants but refuse to document it? If yes, please de-select the "Informed Consent Waiver" in this section and explain about it as a separate "Note" in the "Study Procedures" section of this application.

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

Minimal Risk
Non-English translation required

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.
Federally funded

Enter name of federally-funded source.
Centers for Disease Control and Prevention

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.

Please consider the date of the next full board meeting which will be held on October 3rd, 2025. Please select "10/3/2025" or a date following this date within a few weeks. thanks.

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

10/03/2025

ANTICIPATED PROJECT END DATE

12/31/2030

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 primary (main) site of the study in this section.

Note: The main site(s) of the study is/are the institution(s) responsible for the primary storage, receipt, management of study data, and accountable for ensuring data security and compliance with relevant regulations, including overseeing access controls, data encryption, and privacy safeguards—typically housing the servers through which the data is processed.

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There are more than 250,000 ovarian cancer survivors in the US and this number is growing. Throughout treatment for this disease, many patients encounter serious effects, including physical issues like nausea, vomiting, fatigue, sleep disruptions, peripheral neuropathy, hair loss, and sexual dysfunction, as well as psychological challenges such as cognitive dysfunction, fear of recurrence, anxiety, and depression. Comprehensively understanding how the prevalence and severity of side effects, unmet needs, and barriers to supportive care affect quality of life (QOL) in diverse ovarian cancer survivors remains a research gap and priority. Our long-term goal is to improve the survivorship experience of individuals with ovarian cancer. Our overall objective is to document 1) physical and psychosocial concerns, 2) barriers and facilitators to supportive care, and 3) factors associated with unmet needs among ovarian cancer survivors. Our central hypothesis is that ovarian cancer survivors face significant challenges, with differences in the frequency and type of concerns by patient characteristics, e.g., time since diagnosis, age, race/ethnicity, education, income, geographic location, and social support network. Our team at the University of Minnesota, the primary site of this study, will pursue the following specific aims: (1) describe the physical and mental health conditions of ovarian cancer survivors that impact quality of life and detail pharmacologic and non-pharmacologic interventions utilized to manage these conditions; (2) identify barriers and facilitators to accessing and receiving supportive care among ovarian cancer survivors; and (3) describe the unmet needs of ovarian cancer survivors and identify associated risk and protective factors related to the number and types of unmet needs. We will use a mixed-methods approach. We will recruit a representative national sample of approximately 2,000 ovarian cancer survivors in collaboration with the California Cancer Registry to

complete a cross-sectional survey. Among a subset, we will conduct follow-up interviews to gather additional information. The expected outcome of this study is a comprehensive description of survivorship experiences among ovarian cancer survivors which will be shared through manuscripts and presentations.

MAJOR RESEARCH QUESTION

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

We will address the following Specific Aims and research questions:

Aim 1. Describe the physical and mental health conditions among ovarian cancer survivors that affect quality of life and detail pharmacologic and non-pharmacologic interventions utilized to manage these conditions.
-What physical and mental health conditions are ovarian cancer survivors reporting? Do they vary by demographic and clinical characteristics such as age, time since diagnosis, treatments received and current disease status?
-Which physical and mental health conditions are most associated with lower physical and emotional quality of life and higher distress in ovarian cancer survivors?
-What pharmacologic interventions are used to manage these disease and treatment-related symptoms and for whom have these been most successful?
-What non-pharmacologic interventions have been used to manage disease and treatment-related symptoms and for whom have these been most successful?

Aim 2. Identify barriers and facilitators to accessing and receiving supportive care among ovarian cancer survivors.
-What supportive care services/interventions were recommended by a provider?
-What supportive care services/interventions were tried by the survivor? If services were offered but declined, why were they declined?
-What supportive care services/interventions would individuals with ovarian cancer have liked to use but did not, and why?
-What factors facilitated or hindered access to clinical and non-clinical supportive care services?

Aim 3. Describe the unmet needs of ovarian cancer survivors and identify associated risk and protective factors related to the number and types of unmet needs.
-What are ovarian cancer survivors' most urgent unmet needs?
-How frequently are they experienced and do they differ by survivor demographic or clinical characteristics?

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 overall objective of this proposal is to document 1) ongoing physical and psychosocial concerns, 2) barriers and facilitators to supportive care, and 3) factors associated with unmet needs among ovarian cancer survivors. To accomplish this, we will conduct the UNderstanding The experience of Ovarian cancer – Life after Diagnosis (UNTOLD) study using a mixed-methods approach. We will enroll at least 2,000 ovarian cancer survivors to participate in UNTOLD to complete a one-time survey regarding their experiences, with target sample sizes for specific subgroups to ensure diversity in demographics (race and ethnicity, socioeconomic status, sexual orientation, and rural-urban residential location) and clinical characteristics (time since diagnosis, disease stage). We will subsequently identify up to 40 survivors to complete a follow-up interview.

Surveys:
We will utilize mail recruitment of individuals identified through the California Cancer Registry following the Dillman method.

We will request contact information for all individuals in the CCR who have been diagnosed with ovarian cancer from 2014 to 2025 (or most recently available data), excluding those known to have died. We will also request data regarding demographic and clinical characteristics of those who have died to assess potential bias.

For budgetary purposes, of eligible individuals with ovarian cancer in the CCR, we will randomly select 5,000 individuals to send recruitment materials, with oversampling among American Indian/Alaska Native, Non-Hispanic Black/African American, rural, and newly diagnosed individuals. We will utilize recruitment methods outlined by Dillman to maximize response, including multiple personalized, friendly, and attractive mailings with inclusion of an upfront, nominal token incentive (<$5 value). We have previously used this method among cancer survivors to achieve response rates of 40-60%.

The recruitment process will include four mailings:
1. Initial Letter + Incentive: We will mail an invitation letter explaining the study goals with the link to the online survey along with a token incentive. Letters will be personalized and tailored to ovarian cancer survivors. We will explain how we got their contact information and also include a brochure on the CCR per their guidelines. We will also provide a list of emotional health resources available in California. A study telephone number and email address will be provided for participants who have questions or technical concerns. They may also contact the study team to request a paper copy of

the survey.

2.Thank You Card: One week after the study materials are mailed, we will send a thank you card with a friendly reminder to complete the survey, regardless of completion of the survey.

3. Reminder Letter + Paper Survey: Three-four weeks after the initial invitation letter, we will send a reminder letter to non-responders and will include paper copies of the survey and consent/HIPAA form with a postage-paid return envelope. Those who started but did not complete the online survey will also be sent a follow-up letter.

4. Final Reminder: Two weeks after the reminder letter, we will send a final letter to all remaining non-responders.
The study team may additionally follow-up with up with a recruitment phone call between mailings 3 and 4 to encourage completion.

All study participants will be provided informed consent and HIPAA authorization for research forms in accordance with the mode of survey they complete. We will ask participants to fully review these documents but will not request signatures as this would be the only identifiable information linked directly to the survey data. Therefore we will not formally document the consent process. We will also ask participants to indicate if they would be willing to participate in future research studies such as a follow-up interview (optional) and provide contact information accordingly on a separate form from the survey. This information will be stored separately from the survey and we will be unable to re-link them.

All interested study participants will be entered into a drawing for one $200 gift card the week they complete their survey if they provide their contact information (separated from the survey). If selected, the participant will be notified via phone and/or email and sent the gift card via email or mail per preference.

Survey measures.
The surveys will include items for a comprehensive assessment of the study population using reliable and validated measures (survey attached). We prioritized measures that have been previously validated in cancer survivors, while including brief instruments whenever possible.

Clinical and Vitals Data from the CCR. Ovarian cancer diagnosis, treatment and vital status data will be obtained from the CCR for participants and non-participants, including age at diagnosis, disease stage, details on surgery and adjuvant therapies received, treatment status, and whether the disease has recurred. We will collect information related to prior or subsequent cancers and other health conditions. These data will be collected via self-report for all participants, though data related to their ovarian cancer diagnosis and initial treatment will be obtained from the CCR.

Interviews.
Among participants who agree to being contacted for follow-up research, we will invite up to 40 to participate in a 1:1 interview with study staff. We

believe this mixed-methods approach will provide us with a more in-depth understanding of the survey responses and provide additional insights into care gaps, unmet needs, as well as what is helpful for ovarian cancer patients. We will contact participants via phone or email to explain the purpose and procedures of the follow-up interview and recruit interested individuals.

Participants will be asked to complete 30-45 minute interviews via phone or online via Zoom per participant preference. After recruitment and obtaining verbal consent, interviewers trained by Drs. Vogel and Parsons will use a semi-structured guide including open-ended questions (Moderator guide attached). Interviews will be digitally recorded and transcribed verbatim. Individuals will be compensated $50 for completing the interview. Following review by the research team, Community Advisory Board and CDC staff, the interview guide will be assessed after the first five interviews for any necessary changes. If significant edits are made, those interviews will be treated as pilot data and left out of the analysis. We will continue conducting interviews until thematic saturation has been met.

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.

cdc_ovca_survey_20250624_clean.docx	Questionnaires
cdc_ovca_survey_20250624_clean_Spanish.docx	Questionnaires
identifying_sheet_CA_reg20250827.docx	Questionnaires
identifying_sheet_CA_reg20250827_Spanish.docx	Questionnaires
interview_guide_20241231.pdf	Questionnaires
interview_guide_20241231_Spanish.docx	Questionnaires

Deleted Attachments: 7 (Most Recent: Moderator Guide on 08/27/2025 12:51 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.).
Digital recordings from interviews will be stored on secure servers. Following verification of transcipts and publication of manuscript, recordings will be deleted.

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.

Based on the documents attached to your application, it appears that all datasets required for this study will be provided by CDPH/CCR. If that is correct, please confirm this in the "Study Procedures" section of the application and delete the second row referring to VSAC.

Please note that listing VSAC in this section implies that you will be receiving separate datasets from both VSAC and CCR. In that case, a separate support letter from VSAC would be required—similar to the one you've already obtained from CCR and attached in the "Support Letter" section.

To avoid confusion and ensure accuracy, kindly confirm in the "Study Procedures" section that all data will be released by CCR. If this is accurate, please delete the second row that refers to VSAC.
Thanks.

09/03/2025 • Sussan Atifeh • *Not* Internal • Resolved

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	California 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.

Inclusion Criteria:
-Age greater than or equal to 18 years
-Ability to read and write in English or Spanish
-Diagnosed with ovarian cancer (ovarian, primary peritoneal, fallopian tube)

Exclusion Criteria:
-Incarcerated

We anticipate a list of approximately 10,000 potentially eligible participants from the California Cancer Registry and will approach approximately 5,000 to obtain our goal of 2,000 participants. It is our goal to specifically enroll individuals from groups not well-represented in health research, specifically those with lower socioeconomic status, living in rural areas, patients of color, especially Black/African American as well as Hispanic patients, and sexual minorities. These cancer populations are often disproportionately affected by worse survival and survivorship outcomes, symptoms and side effects, and barriers to optimal care. To allow for subgroup analyses, we will enroll until we have at least 200 individuals in each of the following demographic categories: those of Black / African descent, Hispanic, living in a census tract in the lowest quartile of median income in the US, live in rural areas or small/medium towns (based on RUCA code), and at least 100 individuals who identify as a sexual minority.

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.

Databases: California Cancer Registry and Vital Statistics Data for individuals with a diagnosis of ovarian cancer between 2014 and 2025 (or most current data available).

See attached for details regarding variables requested.

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.

Requested_Variables_ADA_20250124.xlsx List of Variables

Deleted Attachments: 1 (Most Recent: CCR_Variable List with Justification_CDC Grant_Ovarian_20250114.docx on 08/27/2025 12:54 PM ET)

RATIONALE

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

Ovarian cancer is increasingly a chronic disease. Almost 250,000 ovarian cancer survivors are alive in the United States (US) today, and with advances in treatment, the number of survivors is growing. No screening tools exist for early detection of ovarian cancer, resulting in over 70% of all new cases being diagnosed at an advanced stage (stage III or IV). While primary therapy is effective, disease recurrence is high, resulting in ongoing treatment burden over the course of many years and therapeutic treatments. Given the evolution in ovarian cancer management, addressing the unique survivorship needs of this population is critical.

The rationale for focusing on California cancer survivors specifically is that the CCR draws newly diagnosed cancer cases from a large, diverse population. Currently, one in eight US residents lives in California. Approximately 38% of Californians are non-Hispanic White, 39% are Hispanic, 14% are Asian American or Pacific Islander, 6% are Black, 3% are multi-racial and less than 1% are Native American or Alaska Natives. More than 25% of the population is foreign born. The population has broad socio-demographic diversity, with 62% of the population between the ages of 18-64 and approximately 35% of the population reporting an annual individual wage of <$30,000 in 2022. California has approximately 2,400 new cases of ovarian cancer each year.

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.

Of eligible individuals with ovarian cancer in the CCR, we will randomly select 5,000 individuals to send recruitment materials, with oversampling among American Indian/Alaska Native, Non-Hispanic Black/African American, rural, and newly diagnosed individuals. We will utilize recruitment methods outlined by Dillman to maximize response, including multiple personalized, friendly, and attractive mailings with inclusion of an upfront, nominal incentive (<$5 value). This process will include 4 mailings: initial letter, thank you card, reminder letter, and final letter. The study team may additionally follow-up with up with a recruitment phone call between mailings 3 and 4 to encourage completion.

We will conduct supplemental recruitment of individuals across the US in collaboration with national ovarian cancer advocacy groups through email listservs and social media.

Attach copies of all recruitment materials.

CDC Thank You Note_20250606.pdf	Recruitment Materials
final_letter_20241231.docx	Recruitment Materials
invite_letter_20241231.docx	Recruitment Materials
invite_phone_script_20241003_submit (1).docx	Recruitment Materials
reminder_letter_20241231.docx	Recruitment Materials

Deleted Attachments: 17 (Most Recent: thank_you_20241003_submit.pdf on 08/27/2025 12:56 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.
Potentially eligible participants will be identified by the California Cancer Registry and through advocacy groups. Those identified as potentially eligible will be mailed and/or emailed the study invitation and will be asked to self-confirm eligibility prior to initiating the study procedures.

Vulnerable subjects, including children and incarcerated individuals, will not be eligible for participation in this study. Pregnant individuals will not be targeted but may be included incidentally. This minimal risk study will pose no serious threat to the pregnant individual or fetus.

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.
Individuals recruited through the CCR will be provided token incentive (<$5 value) regardless of their participation. Because of budgetary constraints, rather than providing payment to all participants, a lottery-based incentive will be used.

Participants will be entered into weekly lotteries for $200 gift cards for the duration of the recruitment period (~36 weeks). The weekly winners will be randomly drawn from all participants who completed the survey that week.

Individuals who participate in the optional follow-up interview will be compensated with a $50 gift card.

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.

The amount of time needed for a participant to complete all study procedures is approximately 1-2 hours, depending on if they participate in the follow-up interview.

Study recruitment is expected to take 9-12 months. The entire study duration, including recruitment, data collection, and analysis will be up to 3 years.

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 study is minimal risk. We identified two possible risks to subjects:

Risk to confidentiality: Inadvertent breaches of confidentiality by investigators or their staff may occur. To minimize that risk, all study staff will undergo appropriate technology and data security training in REDCap. Patients' identifying information will be minimized and kept private. The records will be identified only with a unique ID number on an encrypted database. Data transfer will only occur with de-identified data with encrypted transfer of all information containing protected health information between participants and study databases.

Discomfort with survey questions: There is a possibility that some participants may feel uncomfortable being asked questions related to their cancer diagnosis and effects of treatment. Participants will be reminded they do not have to answer any question they do not want to.

AUDIO/VIDEO RECORDING RISKS

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

It is possible the recording from the interview could increase potential risk to confidentiality. We will follow the procedures outlined above to minimize this risk.

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.

This is a minimal risk study. We could not record the interviews, however, that would compromise the data quality.

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.

There are no expected direct benefits to individual participants. Some participants may appreciate contributing to an ovarian cancer research study that might benefit other patients in the future.

JUSTIFICATION OF RISKS

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

The number of individuals living with ovarian cancer is rising. Given the lack of evidence-based methods for prevention and early detection and poor prognosis, there is a strong need to improve the survivorship experiences of this patient population. A thorough understanding of ovarian cancer survivorship experiences, unmet needs, and care gaps will facilitate interventions to improve the quality of life and even survival in this population. Quality of life is important to cancer patients, with studies showing it matters equally, if not more than, length of life. The minor risks of loss of confidentiality and discomfort with the surveys are outweighed by the importance of the information gained.

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

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 study investigators and staff are fully trained on data safety and participant confidentiality using appropriate CITI and University of Minnesota courses. All investigators and staff will be added to the Unviersity of Minnesota IRB and approved prior to any involvement in the study. The number of investigators/staff involved who have access to PID will be minimized and de-identified data will be used whenever possible.

STAFF VETTING PROCEDURES

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

All investigators and staff are vetted by the University of Minnesota, including a background check at hiring, and all training is confirmed by the IRB. In addition, researchers who need access to Data Shelter (where these data will be stored) need to meet following requirements before they are granted access to data of their specific project:

-HIPAA Training through Training Hub, or other verifiable HIPAA training if the user is an external collaborator
-Signed the Secure Computing Environment Attestation Form or AHC-IE Attestation Form. Additional attestation forms may also be required for specialized access.
-Be named on the associated IRB project, if applicable.
-Be named on associated Data Use Agreements, if applicable.
-Data Steward or Study PI approval
-Authorized user access is reviewed on a regular basis to ensure access is still appropriate and necessary.

User Capabilities in the Data Shelter:
-Users can only access the space that is dedicated for their own projects
-Users can utilize licensed and installed data analysis tools such as SAS, Stata, JMP Pro, R, SQL, Access, Excel, ArcGIS, etc.
-Users can bring other data into the secure environment for integration / analysis using the secure file exchange capabilities in Portunus or through jobs maintained by the HST Data Engineering and ETL team.
-Data files or generated knowledge (data analysis output) that will need to extracted out of the environment will require review to ensure that it meets the criteria of extracting data. Extraction criteria are dependent upon a combination of internal policies plus any data use agreements that the data set would be governed under.
--Review is performed by CTSI Informatics Core in the case that an extraction is requested from the AHC-IE Data Shelter
--Review can be performed by a trusted honest broker on the Study Team in the case that an extraction is requested from the Secure Computing Environment

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.

SIGNED_CPHS_LOS_Vogel, R.docx.pdf	Department Letter of Support
VSAC_notarized_w_AppendixA.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.

The PI will manage the addition of study personnel to the IRB and their access to the data. The data shelter which will be used to store these data has numerous security controls in place which prevent unauthorized personnel from gaining access to the data.

CONFIDENTIALITY OF PUBLISHED DATA

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

We will not publish information that could 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?

We are requesting sufficient data to achieve the necessary sample size for our research study. Justification for inclusion of variables is included in the list of variables. We have minimized our request for identifable variables to only those needed to contact potential participants or for comparisons of those who do and do not participate in the study.

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.

I confirm that the access to the data will be limited to only those with a need to know for purposes of implementing the 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.

Cell sizes of less than 11 will be reported as "<11".

LINKAGES

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

> In other section of the application, you have referred to a linkage and mentioned, "All participants will be assigned a study ID and this ID will be linked to all data. The contact information provided from the CCR will be stored separately. The link between the study ID and participant data will be destroyed after 10 years after the completion of data collection and/or completion of study publications, whichever comes first."
>
> Please re-check your response in this section.
>
> 09/02/2025 • Sussan Atifeh • *Not* Internal • Resolved

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.
We will create a study ID (one variable) to serve as a link between the CCR data and participant survey data. This will allow us to make comparisons of cancer registry variables between those who do and do not participate in the survey.

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.
No answer provided.

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_requirements_letter_20241114_signed.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.
All participants will be assigned a study ID and this ID will be linked to all data. The contact information provided from the CCR will be stored separately. The link between the study ID and participant data will be destroyed after 10 years after the completion of data collection and/or completion of study publications, whichever comes first. The data provided in the publically available dataset will be fully de-identified, which is completed by the PI and reviewed and confirmed by data repository staff prior to data release.

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.

Any paper forms with PID will be properly destroyed using cross-cut shredding in alignment with University policies for desctruction of documents including PHI.

FAXING

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

Faxing will not be used.

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.

Our study team will be conducting the mailing and they will not be batched. PID will be sealed and secured from view.

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 in paper or electronic form will not 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.

Data will be stored in the PI or study coordinator's locked office in a locked cabinet in a buliding that is guarded and only accessible by ID card.

SERVER SECURITY

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

Files will be maintained in The UMN Academic Health Center Secure Data Shelter which has been established by the University of Minnesota through its Clinical Translational Sciences Institute to provide a secure environment that can consume, aggregate, transform and enrich sensitive data sets for research purpose. The Data Shelter is a PHI compliant environment that is managed by UMN CTSI Informatics Core team along with the Health Sciences Technology office, part of the Office of Information Technology. The PHI-compliant environment (architecture and data governance policies) are audited by UMN IRB, Health Information Privacy and Compliance Office, Center of Excellence for HIPAA Data, CTSI Biomedical Informatics Program (BIMP), and data stewards for security auditing.

The Data Shelter is a series of remote servers built for the purposes of analyzing and working with PHI data sets. Data Shelter servers are segregated from the rest of the University network through the use of firewalls. Data is encrypted at rest. Data is transmitted to the Data Shelter servers using a combination of secure ftp, https, and secure VPN connections. Internet / network access from within the data shelter is limited, making the transmission of data outside the shelter impossible. All entry points to the Data Shelter require two-factor authentication. User password resets are required every one-hundred fifty days. Terminal server sessions lock out connections after fifteen minutes of inactivity and requires two-factor authentication to unlock the session.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Identifiers, with the exception of dates and geographic variables necessary for analyses such as zip code, will be stored separately from analysis data.

DISK STORAGE

State whether all disks with PID will be destroyed.

Data will not be stored on disks.

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 password protected and server access requires VPN with DUO two-factor authentication.

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.

I confirm all workstations that contain PID have full disc encryption use 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.

PID will not be stored on a laptop.

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 placed on removable media devices.

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 and laptops with access to this PID are managed by the University of Minnesota Academic Health Center IT team and will 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 entry points to the Data Shelter require two-factor authentication. User password resets are required every one-hundred fifty days.

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.

We confirm the following electronc security controls are in place: 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.

No transmissions of electronic PID occur outside the secure internal network.

INTERNET ACCESSIBILITY

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

The PID wil 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.

Phyiscal 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.

Individuals who participate in the survey study and potential follow-up interview will review and be provided written informed consent materials (electronically or paper depending on recruitment method), however, the documents will not be signed by either research staff or the participant. Potential participants will be encouraged to contact study staff for more information before deciding whether or not they would like to participate in the study.

We request the waiver of documentation of written consent because this would be the only link between subjects and research (survey data) and we do not want to risk potential harm resulting from a breach of confidentiality. This would allow us to keep all identifying information completely separate from survey data.

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.

combined_consent_hipaa_20250606_tracked.pdf Consent Form

Deleted Attachments: 4 (Most Recent: combined_consent_hipaa_20250606_tracked (1)_Spanish.docx on 08/27/2025 1:10 PM ET)

TRANSLATED DOCUMENTS

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

combined_consent_hipaa_20250606_tracked (1)_Spanish.docx	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.

Letter of Certification_P-2025-3024.pdf	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?

Please check with CCR to ensure the requested data is covered under HIPAA. If the requested data is not covered by HIPAA, please change your response in this section to "No."

09/02/2025 • Sussan Atifeh • *Not* Internal • Resolved

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

sip_budget_CCR_app.docx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

cover_letter_PIs_20250210.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 12:42:49 PM ET by Rachel Vogel, 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.

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

California Department of Public Health: California Cancer Registry

Responsible Official Signature
- Submitted 09/01/2025 4:40 PM ET by Colleen Rivard, MD

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 Monday, September 1, 2025 4:40:02 PM ET by Colleen Rivard, MD

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 09/04/2025 4:45 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
This project has involvements of human subjects' contacts and should be discussed in the upcoming full board meeting.

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 09/04/2025 4:46 PM ET by The System

Chair Review and Full Board Set-Up

Full Board Set Up

Project number

2025-131

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.