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 05/03/2024 8:57 PM ET by Ann Hamilton, PhD

Amendment Header

Amendment Submitter

June 2024 cycle
05/06/2024 • Nicholas Zadrozna • Internal

Ann Hamilton, PhD
Email: ahamilt@med.usc.edu **Business:** (323) 865-0434

Instructions for amending your approved application:

This is a copy of the project application in order to amend the project. You must answer all the amendment questions. After you've answered those questions, you will have to update all answers on the form that related to your proposed changes. You may leave other questions with their original answer. If you do not update the appropriate responses on the form related to your proposed amendment, you will be required to make additional changes.

Note that the contacts listed on this page are output only questions that cannot be changed. If you need to request personnel changes, you will be prompted later on within this form to enter the new contact information.

PI:

Ann Hamilton, PhD
Email: ahamilt@med.usc.edu **Business:** (323) 865-0434

Administrative Contacts:

Name	Role

Protocol Number:

2023-123

Protocol Title:

Risk Stratified Survivorship Care Pathways for Early-Onset Colorectal Cancer (the Survive-CRC Study)

Indicate what types of changes you are requesting to this project. Select all that apply

Recruitment strategy and/or materials
Research methodology and/or research questions
Additional data sets requested
Population, sample size, inclusion/exclusion criteria
Addition and/or removal of project personnel
Data collection
Other (examples such as, but not limited to: budget changes, project site and project title)

Clearly summarize and justify your proposed changes to the protocol in layman's terms for all selections made above

I obtained the CPHS Chair's signature on the Reliance agreement form (attached), and submitted it to the USC IRB. I have received (and attached) the USC IRB's agreement to cede authority to the CPHS.

May 3, 2024. We previously obtained approval for Aim 1 of the study that involved review of path reports and did not involve patient contact. Now we are requesting approval for Aim 2 which includes a patient survey and a different sample of patients. We have submitted the survey, letters, protocol, and other documents associated with Aim2.

We would also like to change the title of the study to: Survivorship Care and Recurrence Risk Evaluation for Early-Onset Colorectal Cancer Patients-SURVIVE CRC Study

We have added Dustin Tan as a staff member who will be involved in administration of the survey.

Indicate the Level of Risk involved with the changes proposed.

If level of risk has changed, please update the "Risks" section in the protocol form.

Level of Risk has not changed

PI City Output *(Internal)*

Los Angeles

PI Location State Output *(Internal)*

California

Personnel Information for Amendment

Please complete the questions below.

If while trying to complete those questions, personnel are not found by their email address, you can add them in the system by completing the 'new contact form'. Click on the 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.

New Contact Form

Existing Personnel

Name	Role
Ann Hamilton, PhD	Principal Investigator
Denise Modjeski, MS	Research Team
Howard Hu, ScD	Responsible Official
Susan Largent, MD	Research Team

Will you be making any changes to the makeup of research personnel?

Addition of other Research Staff

Please click 'Add Contact' and add any other research staff.

Dustin Tan, BPH
Email: dustinta@usc.edu **Mobile:** (323) 442-0759

Project Information

SUBMITTER

Application completed by:

Ann Hamilton, PhD
Email: ahamilt@med.usc.edu **Business:** (323) 865-0434

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).

Survivorship Care And Recurrence Risk Evaluation For Early-Onset Colorectal Cancer Patients-SURVIVE CRC Study

STUDY PROCEDURES

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

Data Registry
Recruitment-Participant
Surveillance Data
Surveys

TYPE OF RESEARCH REQUEST

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

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

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

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

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

Common rule/Human subjects

PROJECT TYPE DETAILS

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

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

Minimal Risk
Non-English translation required
HIPAA waiver
Consent form
Reliance Agreement relying on CPHS

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

Link to Authorization Agreement for Organization Without an IRB

AuthAgree_ Hamilton.pdf	IRB Reliance on CPHS
USCIRBAapprovalSurvive-CRC Study 8.29.23.pdf	IRB Reliance on CPHS

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.

Not applicable

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Federally funded
University funded

Enter name of federally-funded source.
NCI

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.*

New project requesting only previously existing PHI/PIDs and not involving state research staff, funding or state mental hospital patients from departments within the CHHSA (Common Rule review)

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

09/01/2023

ANTICIPATED PROJECT END DATE

08/31/2028

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.

Over the past two decades, the incidence of colorectal cancer among adults < 50 years of age (i.e., early-onset CRC) has been increasing, however, survivorship care has evolved slowly and remains poorly informed and of suboptimal quality. Thus, there is a critical need to design a model of survivorship care that aligns: 1) the intensity of surveillance with actual risk of recurrence; and 2) the provision of care services with need. Stratified survivorship care pathways provide an opportunity to deliver patient-centered, high-quality care that is appropriately tailored to individual needs. However, these pathways currently do not exist for patients with early-onset CRC, which is in part due to the lack of population-based estimates of recurrence that can guide surveillance approaches and the dearth of knowledge regarding these patients' unique survivorship care burdens and needs. In this proposal, we will identify patterns of recurrence among patients with stage I-III early-onset CRC, generate population-level estimates of risk of recurrence, and examine clinical and sociodemographic factors associated with recurrence risk (Aim 1). May 2024 amendment: We will then survey a cohort of patients diagnosed with early-onset CRC to assess patients' receipt of surveillance and self-reported survivorship care needs across multiple domains (Aim 2). This grant is a subcontract with Dr. Wallner from the U. of Michigan who is the overall PI and will be conducted at USC for the Los Angeles cases. In addition to Los Angeles cases, the study will include cases from Georgia and Kentucky. The Los Angeles Aim 1 work will take place at the USC Keck School of Medicine. A dei-identified research file will be provided to Dr. Wallner at U. Mich. for analysis.

MAJOR RESEARCH QUESTION

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

Are patients with early onset colorectal cancer receiving appropriate survivorship care based on their clinical factors and how many experience recurrence?

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

There are two aims for the project. At this time we are requesting approval for Aim 1 only, which will involve review of path reports and other methods to identify recurrence in patients diagnosed with early stage CRC between 2015-2018 from the Los Angeles Cancer Registry and will not involve patient contact.

We are now (May 2024) submitting an amendment for the second Aim will involve a survey of cases diagnosed in 2019-2023 and we have uploaded the survey, letters, and other materials.

The creation of data for Aim 1, including medical record review, abstraction from path reports, linkage to CoC and mortality data will be stored at USC and will be linked by a study ID. A de-identified research file that will include the variables abstracted from each source and cancer registry variables will be sent to Dr. Wallner at U. Michigan for analysis. Previous similar such studies have not required a separate Data Security Letter from the site where analysis is done since they will be signing the CCR's Appendix 3 and their data security is included in their U. of Michigan IRB review. Also no personal identifiers are sent to U. of Mich. However, if this is a new requirement I will request it and add it as an amendment.

Procedures for Aim 1:
1) the LA-SEER Cancer Registry will use routine case ascertainment to identify all patients <50 years of age with incident Stages I-III CRC in diagnosis years 2015-2018 as reported to the LA County SEER registry (total n=1675).
2) USC staff will abstract key clinical cancer and demographic variables and employ a multi-pronged methodology to identify recurrences in the 5-year period following initial diagnosis, including data from the following sources:

1) SEER pathology and available pathology reports
We will abstract both electronic and hard copy (as needed) reports for all pathology reports identified over the 5-year post-diagnosis period and manually review them for evidence of recurrence. We estimate the need to manually review reports for 25% of selected cases (n=419) (See attached path review form).
2) Commission on Cancer (CoC) hospital recurrence data
We will utilize the CoC-Los Angeles SEER data linkage to identify any additional recurrences not captured via pathology reports
3) SEER mortality data
We will use linked data from state vital records and National Death Index Files to identify any patients who later died from CRC. These patients will be considered to have experienced recurrence or progression to metastatic disease.

We will identify rates of CRC recurrence within five years and characterize patterns of recurrence. De-identified data will be shared with U. of Michigan investigators for analysis.

Aim 2 (included in the May 2024 amendment)
The LA-SEER will identify by both routine and rapid case ascertainment a sample of 1000 adults aged <50 years who were diagnosed with incident Stages I-III CRC in diagnosis years 2019-2023. African American, Asian, and Latina patients, and patients with stage III disease will be oversampled. Selected patients will be mailed surveys to assess patient-reported receipt of surveillance care and survivorship care needs

Fieldwork procedures are as follows:
Survey Fieldwork
1) LA County Cancer Surveillance Program will select sample of 1000 cases according to study guidelines
2) A tracking database will be established to monitor the fieldwork and create reports on study progress.
3) Subjects will be able to complete the survey by paper, or online (or by telephone if requested). The online survey will be created in Qualtrics by the University of Michigan but hosted separately at USC, so only USC staff will have access to our own dashboard containing survey response and participant information. University of Michigan investigators and staff will not have access to any patient PII or PHI during the course of this study.
4) Prior to mailing of the survey packet, sites will remove any patients known to be deceased and will trace addresses to assure that current addresses are being used.
5) Sites will mail a survey packet to each patient in the sample in batches over a 10-month time period (approximately 100 packets mailed each month per site).

The survey packet contains:
a. An introductory letter (see Recruitment Letter attachment) that describes the study and includes the URL ad QR code and patient-specific log-in information (Access Code) for the online survey option.
b. A research information sheet that describes the steps taken to assure participant confidentiality and includes contact information for the study team and the IRB
c. A paper copy of the survey (see survey attachment) and a postage-paid envelope for returning it
d. A $20 gift card

We need to submit an amendment for Spanish language study materials, including a survey will be included in the packet for patients with Spanish surnames. A Spanish language version of the online survey will be made available. Until approved, we will not include Spanish Surnamed patients in batch mailings.

6) We will use the tracking database to track receipt of completed surveys, monitoring the online survey completion dashboard as well as incoming paper surveys.
a. If the patient has not completed a survey within 2 weeks after the initial mailing, USC study staff will call the patient to answer questions and encourage them to complete the online survey (or the paper survey if patient is hesitant or unwilling to do the online survey). Study staff will ask for the patient's email address in order to send them a direct, clickable link to the online survey, though patient provision of email address will not be required to take part in the study. Study staff will also offer a telephone interview option. At least 5 calls will be made to reach the patient, including nights and weekends as necessary.
b. If patient is unable to be contacted, Study staff will conduct additional tracing to try and find an updated mailing

address and/or phone number.
c. 2 weeks later, if patient still has not completed the survey and has not opted out, Study staff will send a reminder email (if email provided) or a reminder letter encouraging online survey completion or completion by paper survey followed by 3 phone calls.
d. 2 weeks later, if still unsuccessful, a second copy of the survey packet (minus the incentive) will be sent followed by 3 phone calls.
e. 2 weeks later, if still unsuccessful, Study staff will make a final attempt to encourage survey completion via phone calls, emails, and reminder letters (depending on how participant was able to be contacted previously) containing the link and log-in information (Access Code) for the online survey .

Missing Data Protocol
In some instances, a respondent will send back a survey with some pages left blank. In cases where an entire page(s) of the survey is skipped, S
Study staff will attempt to call these respondents to obtain answers to the missing questions. In some cases, copies of the blank pages would be mailed to the participant to complete along with a postage paid return envelope.

If the respondent writes "skip" next to the item or otherwise indicates an unwillingness to answer it, a call back is not needed. Likewise, content deemed sensitive – including but not limited to questions regarding sexual functioning, income, gender identity, or sexual orientation – will not require a call back.

Survey Data Handling
All data for this study will be stored on password-protected servers and/or in locked filing cabinets. Only designated study staff and investigators will have access to study materials.
Sites will collect and securely store patient contact information provided by patients during the course of this study and used to manage survey follow-up efforts (i.e., phone number, email address). This contact information will be retained by the USC site and never transmitted to University of Michigan investigators and staff.
USC staff will strip patient paper surveys of any PII that may have been written in by the respondent prior to transfer to the University of Michigan. Electronically-completed surveys will reside on the University of Michigan-hosted Qualtrics server and will not collect PII or PHI.
Sites will send paper surveys to the University of Michigan via Fedex for double data entry at regular intervals. Paper surveys will not contain any PII .

7) Only a limited dataset (with no PII) will be shared with the University of Michigan study team.

SEER Data Linkage
At the conclusion of the study, once all survey data has been collected and the sites have concluded follow-up efforts for the study, the sites will provide the University of Michigan study team with a SEER data file from their registry database of patients in the study sample. The file will contain cancer diagnosis and treatment information, urban/rural residence classification codes, and updated vital status information for all patients in the study sample – such as survival status and cause of death. This file will not contain patient identifiers (PII) and will only contain the Study ID of each patient, diagnosis and treatment information, codes for either rural or urban residence, and vital status information. The University of Michigan analytic team will merge the SEER data with the survey data using the Study ID number.

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.

Path Report Review Form.docx	Other Documents
Survey_Draft10_SURVIVE-CRC-USC.pdf	Questionnaires

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	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.

Aim 1 will include all patients <50 years of age with incident Stages I-III CRC in diagnosis years 2015-2018 as reported to the LA County SEER registry (total n=1675). (no selection is made related to age, sex or ethnicity since all patients meeting the selection criteria will be included).

Aim 2- described in May 2024 amendment, will include a sample of 1000 adults aged <50 years who were diagnosed with incident Stages I-III CRC in diagnosis years 2019-2023. African American, Asian, and Latina patients, and patients with stage III disease will be oversampled. These cases will not be included in any other study.

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.

The registry variable list for Aim 1, including text fields, is included as an attachment. We will also request mortality data (Attachment A)

For Aim 2, we will request the same registry variables as indicated for Aim 1, and also request patient contact variables in order to send the recruitment letter and survey packet to the sampled cases.

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.

Attachment A_Survive-CRC_Study.docx	List of Variables
Patient contact variables.docx	List of Variables
SURVIVE CRC SEER variable list.xlsx	List of Variables

RATIONALE

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

The study is investigating recurrence, treatment and survivorship among those with early onset colorectal cases and all the available cases are needed to address the aims. In addition to Los Angeles cases, the overall study will also include cases from Georgia and Kentucky to reach the desired number.

Patient reported experience with the treatment they have received and problems experienced from their colorectal cancer will be obtained from the patient survey. A more recently diagnosed group of patients will be selected.

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.

No patient contact is occurring for Aim 1.

Cases for Aim 1 are being selected from the cancer registry.

For Aim 2, 1000 patients will be selected from the cancer registry meeting the sampling criteria:
if 21041<=SEERWHO<=21052 and
2019<=yeardx<=2023 and
18<=age<=50 and
'10'<=STAGE_SEER<='39' and
SEQNOCEN in ('00','01') and
'10'<=SURGPRIM<='90' and
histo_t3 notin /*excluding the carcinoids*/
('8013','8041','8051','8070','8071','8072','8083','8240','8241','8246','8249','8380','8720','8800','8815','8858','8890','8936','8980');

They will learn about the study by first receiving the recruitment letter and research information sheet included in the survey packet. A brochure from the CCR will also be included to inform them about the cancer registry and how we obtained their name. See Study protocol section for additional details on recruitment. A reminder letter will sent if needed, verbal script will be used for phone calls, and email text is provided if we have previously obtained their email or phone number and have permission to text them. (An amendment will be submitted with the Spanish language versions of these attachments).

Attach copies of all recruitment materials.

CCR English research brochure.pdf	Recruitment Materials
InformationSheet_SURVIVECRC_20240503-USC.docx	Recruitment Materials
PatientFollow UpCallScript_20240503-USC.docx	Recruitment Materials
Recruitment Letter USC-5.03.2024.doc	Recruitment Materials
Reminder Recruitment Letter USC-5.03.2024.doc	Recruitment Materials
SURVIVE_survey email reminder USC-5.03.2024.docx	Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

No

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Cash

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.
There will be compensation for cases selected for Aim 2, but no compensation in included for Aim 1.
Aim 2 cases will receive a $20 gift card up front included in the survey packet mailing. They may keep the gift card whether or not they participate.

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.

No patient contact is involved for Aim 1.

The involvement of subjects for Aim 2 is limited to the time it would take them to complete the survey, which is estimated to be 45 minutes.

Risks and Benefits

RISK DESCRIPTION

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

Overall risks are minimal for Aim 1 because data will be collected from registry, hospital, path report, and mortality data and kept confidential. All data sources will be linked by a study id and no personal identifiers will be kept in analytic files. The greatest potential risk is loss of confidentiality related to personal health information.

Risks for Aim 2 include possible loss of confidentiality and possible psychological stress in completing questions about their cancer treatment and it's impact on their quality of life. However they are instructed to skip any question that they do not want to answer.

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.

This is a non-invasive, no patient contact study for Aim 1 and there are no other methods that are less risky than the ones being used. Aim 2 will only involve a patient survey that can be completed when convenient for the patient. They can skip any question they do not wish to answer. Thus this is a minimal risk study.

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 direct benefits to the patient subjects in Aim 1 as they are not involved directly.

There are no direct benefits to the subjects in Aim 2 other than the knowledge that they have contributed to research that may help cases diagnosed in the future and could contribute to improving survival and quality of life of other cancer survivors.

JUSTIFICATION OF RISKS

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

The study risks due to loss of confidentiality and psychological stress are minimal compared to the information to be gained from the study

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

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

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

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

HIPAA IDENTIFIERS

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

Name
Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
Telephone numbers
Email address
Social Security Number
Medical record number

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.

Staff are required to have IRB and HIPAA certification to participate in the study. They also take confidentiality training administered by the Los Angeles Cancer Surveillance Program and sign confidentiality pledges.

STAFF VETTING PROCEDURES

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

All employees hired by USC undergo a background check.

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.

CPHS_LOS_Hamilton, A.docx.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.

All data will be kept on secure servers and not released to any unauthorized person or entity. Dr. Hamilton will assure that she will not release data for any other purpose by signing the CCR's Appendix 3. Dr. Wallner has also signed CCR's Appendix 3.

CONFIDENTIALITY OF PUBLISHED DATA

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

No publications will included individual's names or allow for identification of an individual. All results will be presented in tabular fashion.

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 have assessed the number of cases required to meet the study's goals. The sample selection and power of the study were reviewed by NCI as part of the grant review process.

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.

Access is limited to only staff who need to select the cases according to the eligibility criteria and to implement the research.

UNIQUE IDENTIFIERS

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

SSN's will only be used to trace lost individuals. The sources for tracing (Lexus Nexus) use SSNs to provide updated addresses from their databases. Without using them we make obtain addresses to the wrong individual (e.g. someone with the same name).

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 under 5 cases will be suppressed in any publication.

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.
The CoC data and Mortality data will be linked to the cases to determine recurrence. These datasets are linked to the California Cancer Registry data as part of routine procedures. We will obtain permission to access the mortality data from VSAC. The variables include information on mortality due to colorectal cancer and date of death. The CoC data includes dates of subsequent procedures received by the patient related to recurrence of their early stage CRC.

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*

Ann Hamilton - Survivorship for early onset colorectal cancer (002).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 contain personal identifiers

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.

Cross cut shredding

FAXING

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

FAX machines are in secure areas. We will use sfax, an electronic method of faxing requests to providers, thus paper copies will not be required. Any faxes with PID will not be left unattended. Computers are password protected

MAILING

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

Any mailing of PID to request medical records would be sealed and protected, marked as confidential, and sent with a tracking number. There would be no mailings of 500 or more of individually identifiable records 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.

Any PID on paper or electronic form stored on laptop computers or portable electronic storage media will never be left unattended to 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.

All facilities which store PID in paper or electronic form at USC are protected by controlled access procedures and have necessary protection as required.

SERVER SECURITY

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

All servers at USC are protected by controlled access procedures and have necessary protection as required.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Identifiers will be stored separately from analysis data. With regard to retaining data with personal identifiers, in Los Angeles, a file that links personal identifiers to the study id will be maintained in order to link these cases to mortality data to be obtained later. These identifiers would include name, date of birth, and registry Patient ID and Study ID. This cross walk file would be maintained at USC for up to 10 years to allow for longer term follow-up. However, in the research database that Dr. Wallner (U of Mich) will have access to for analysis, no personal identifiers will be included.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID will be destroyed.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All computer access is protected through use of encryption, passwords and other protections.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

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

Yes all workstations have full disc encryption that uses FIPS 140-2 compliant software.

FIPS 140-2 COMPLIANCE: LAPTOPS

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

Yes all laptops have full disc encryption that uses FIPS 140-2 compliant software.

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

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

Yes all removable media devices have full disc encryption that uses FIPS 140-2 compliant software.

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 workstations and laptops are updated daily with security software.

PASSWORD CONTROLS

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

Yes sufficiently strong passwords are in place and are required to be changed on regular basis.

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, these security controls are in place.

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, PID will be transmitted outside the secure internal network.

INTERNET ACCESSIBILITY

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

No, PID in electronic form 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.

Yes, physical destruction or sufficiently secure wiping 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.

No informed consent procedures are required for Aim 1.

For Aim 2 we have included a research information sheet that includes the elements of an informed consent. The participant is told that by completing and sending back the survey they are consenting to participate. They will be receiving the materials in their own home and can make the decision if they wish to participate at any time they choose. They are provided with PI and study coordinator phone numbers to call if they have questions. We will be providing a Spanish translation of the research information sheet and the translator certificate in another amendment.

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.

InformationSheet_SURVIVECRC_20240503-USC.docx Consent Form

TRANSLATED DOCUMENTS

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

Translation placeholder.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.

Translation certificate placeholder.docx Translator Curriculum Vitae

HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Amendment Changes

List the pages and questions that have been changed.

P. 2 Added research personnel-Dustin Tan
P. 3 Project title-revised
P. 3 Study procedures-checked additional boxes related to patient recruitment
P. 3 Type of research request-checked common rule/human subjects
P. 3 Project type details-checked non-English translation and consent forms. unchecked informed consent waiver.
P. 4 Purpose-indicated that this amendment is addressing Aim 2
P. 4 Study procedures-Described procedures for Aim 2, attached survey
P. 5 Population description-Indicated Aim 2 included in this amendment
P. 5 Database details- Added patient contact variables for Aim 2
P. 5 Rationale-added information about rationale for Aim 2
P. 5 Recruitment details-added information for Aim 2 and uploaded recruitment materials
P. 5 Compensation-described $20 gift card to be provided for Aim 2
P. 5 Study Duration-indicated that survey would take 45 min.
P. 6 Risk description- described risks for Aim 2
P. 6 Benefits- described benefits for Aim 2
P. 7 HIPAA identifiers-checked additional boxes for telephone, email, and SSNs
P. 7 Preventing Re-Use and unauthorized access-indicated Dr. Wallner has signed Appendix 3
P. 7 Unique identifiers- justified use of SSNs for tracing only
P. 11 Informed consent procedures- Described use of research information sheet for Aim 2
P. 11 Consent forms-uploaded copy of research information sheet

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

Budget_Hamilton_UofMi_R01_Sub_01.2022reduced5-11-23.xlsx	Project Budget
USCBudgetJustification WallnerR01EarlyCRC1-10-22.docx	Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

CPHS_Cover_Letter_HamiltonAim 2-5.03.pdf Cover Letter

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

Notify IRB for Pre-Screening
- Submitted 05/06/2024 6:23 PM ET by Nicholas Zadrozna

Internal IRB Screening

The questions on this page will be blank when an amended copy is submitted. If the form is returned during the amendment review, the questions on this page will appear as answered previously during the amendment review (responses from the initial review will not appear)

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
Researchers requesting approval for Aim 2 which includes a patient survey and a different sample of patients. They have submitted survey's, letters, protocol, and other documents associated with Aim2.

Choose the CPHS Chair
Darci Delgado, PsyD

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

Assign to Cycle

June

Assign to cycle year
2024

Load into IRBManager (Amendment)
- Submitted 05/06/2024 6:23 PM ET by The System

Chair Review and Full Board Set-Up

Full Board Set Up

Project number

2023-123

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.