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 11/27/2024 3:43 PM ET by Sussan Atifeh

Amendment Header

Amendment Submitter

Sophie Zhang, MPH

Email: szhang@crgc-cancer.org **Business:** (916) 779-0284

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:

Arnold Potosky, PhD

Email: arnold.potosky@georgetown.edu **Business:** (202) 687-3228

Administrative Contacts:

Name	Role

Protocol Number:

2024-094

Protocol Title:

Tracking Health and Responses to Living with Cancer (THRIVE 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
Population, sample size, inclusion/exclusion criteria
Data collection

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

Please provide significantly more detail about the RCA data collection. Will this be used for recruitment? How are pathology reports obtained? Where does this data come from? Cancer patients can opt out of participation in the CCR, can they opt out of having their pathology reports shared?

12/02/2024 • Catherine Hess, PhD

In this amendment, we include:

1) The addition of an End-of-Day Assessments (EODA) sub-study

To collect more granular data on change over time in health-related quality of life (HRQOL) and symptomatic adverse events (SymAEs), we will also conduct brief (<5 minute) end-of-day assessments (EODAs) in a subset of participants who have completed baseline (n=160 participants) through the 4-month follow-up (T2). We will enroll 160 participants for this pilot sub-study, and will stratify enrollment by age at the time of mCRC diagnosis (i.e., ≤50 years v. >50 years) and site (i.e., NJSCR v. CRGC). Participants will complete EODAs every 3 days for approximately 14 weeks (between T1 and T2), for a total of 32 EODAs. We have selected this assessment schedule to balance participant burden and density of EODA data. These brief surveys will take less than 5 minutes to complete and will ask about HRQOL, SymAEs, symptom management strategies, and positive experiences specifically in the last 24 hours.

Following completion of baseline, a sub-sample of up to 400 baseline participants (with the goal of enrolling n=160 EODA participants) who have opted to receive electronic study follow-up reminders will be contacted via email and/or text about the EODA sub-study. In case there is an insufficient number of participants who opt into electronic contact, we plan to contact participants who did not opt in to electronic contact via mail until we are able to enroll n=160 participants.

2) The addition of rapid case ascertainment (RCA) to identify eligible individuals via pathology reports

In case of insufficient eligible cases identified via early case ascertainment (ECA), which involves use of processed registry data for sample selection, we plan to use rapid case ascertainment (RCA) using pathology reports to identify eligible cases. For eligible cases identified via RCA, physician notification will be sent to providers treating such cases prior to contacting them.

3) Submission of study materials for review, as mentioned in our initial application:

- 4-month Follow-up Survey
- Text/email scripts directed to participants who opted into receiving

electronic reminders

Summary of changes made to the application:

In "Project Details > Study Procedures"

- Added procedural details about the EODA sub-component.
- Attached EODA contact materials: (1) EODA Cover Letter, (2) EODA Study Information Sheet, (3) EODA Enrollment Form, and (4) EODA Survey.
- Attached study materials as mentioned in our initial application: (1) 4-Month Follow-up Survey, and (2) Text/Email Message Template.

In "Study Population > Population Description":

- Added information about eligibility criteria for the EODA sub-component of the study.
- Added information about the use of rapid case ascertainment, using pathology reports to identify eligible individuals.

In "Study Population > Recruitment Details":

- Added information about recruitment procedures for the EODA sub-study.
- Attached EODA contact materials: (1) EODA Cover Letter, (2) EODA Study Information Sheet, (3) EODA Enrollment Form, and (4) EODA Survey.
- Added information about the use of rapid case ascertainment, using pathology reports to identify eligible individuals.
- Attached physician notification materials used for RCA cases: (1) Physician notification letter, and (2) Physician notification form.

In "Study Population > Compensation":

- Added information about additional compensation for individuals participating in the EODA sub-component — EODA participants will receive $5 per completed EODA survey. Incentive payments will be made via gift card in monthly installments.

In "Study Population > Study Duration":

- Added information about the time commitment for individuals participating in the EODA sub-module — EODA participants will receive brief (<5 minute) surveys every three days for a maximum period of 14 weeks. Participants will be able to select a preferred time between 5pm and 10pm in which they will receive EODA surveys.

In "Informed Consent Procedures > Informed Consent Procedures":

- Added details about additional informed consent materials used to enroll individuals in the EODA sub-component of the study.
- Attached the informed consent materials for EODA to this section: (1) EODA Study Information Sheet, and (2) EODA Enrollment Form.

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

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
Albany Magallanes	Research Team
Anna Shaw, MPH	Research Team
Anshu Shrestha, PhD, MPH	Research Team
Anshu Shrestha, PhD, MPH	Co-Principal Investigator
Arnold Potosky, PhD	Principal Investigator
Carmela Lomonaco, PHD	Responsible Official
Dimitra Fellman	Research Team
Sophie Zhang, MPH	Coordinator
Sophie Zhang, MPH	Research Team

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

*No change in personnel

Project Information

SUBMITTER

Application completed by:

Sophie Zhang, MPH
Email: szhang@crgc-cancer.org **Business:** (916) 779-0284

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).

Tracking Health and Responses to Living with Cancer (THRIVE 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

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

Enter name of federally-funded source.
NIH/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.*

Not applicable

ANTICIPATED PROJECT START DATE

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

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

06/19/2024

ANTICIPATED PROJECT END DATE

12/31/2033

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.

With improving cancer treatments, patients with metastatic cancer are living longer. However, there is limited knowledge about the patient-reported outcomes and survivorship care needs of persons living with metastatic cancer, including colorectal cancer. To address this research gap, we will conduct a population-based perspective study, Tracking Health and Responses to Living with Cancer (THRIVE Study), which will involve surveying 1600 adults living with metastatic colorectal cancer over a one-year period from parts of California and New Jersey. This application to CPHS is for the recruitment efforts that will be done at Cancer Registry of Greater California (CRGC) to recruit up to 900 adults within its catchment areas (i.e., 48 counties out of 58 counties in California). Overall PI of the project is Dr. Potosky at Georgetown University.

The recruitment team at CRGC (led by Dr. Shrestha) will participate in the development of sample selection criteria, study materials and recruitment procedures necessary, implement sample selection, contact eligible individuals to enroll in the study and collect survey data and Medical Record Release form and consent to allow the CRGC staff access to their medical records relevant for their cancer care for additional data abstraction, and mail incentives to those who participate. These data will be de-identified prior to securely transferring them to Georgetown University for data processing and analysis.

In addition, CRGC will use crosswalk between patient and study identifications to provide de-identified registry data on participants linked to their collected data. Registry data on sociodemographic characteristics, tumor/clinical characteristics and initial treatment information will be included as additional predictors of outcomes of interest or confounding factors.

Multiple manuscripts will be developed to disseminate study findings. The study findings will provide novel evidence-based information on this topic and help inform and guide the design of future interventions at both the individual and health care system levels to improve health outcomes for those with metastatic cancer.

MAJOR RESEARCH QUESTION

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

The main goal of this study is to longitudinally document patient-reported outcomes in a diverse cohort, identify high-risk subgroups, and produce the necessary knowledge base to inform multi-level interventions specifically designed for persons living with this disease. In particular, the study aims to:

1. Describe the prevalence, severity, and trajectory of patient-reported symptomatic adverse events (SymAEs) as well as association between SymAEs and sociodemographics (e.g., age, sex, race-ethnicity) and clinical factors.
2. Evaluate the longitudinal relationships between SymAE clusters (and individual AEs that do not belong to any cluster) and patient reported outcomes (PROs), including physical, emotional, and social function (health-related quality of life; HRQOL).
3. Assess the longitudinal association of multi-level (individual and healthcare system) factors with PROs. Guided by self-management frameworks, we will test hypotheses regarding the association of mutable personal characteristics, such as self-efficacy for managing chronic conditions or social support, as well as access to palliative/supportive care, care delivery and access and cost sharing with improved PRO trajectories.

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

Below are procedures for three activities:
1. Implementation of recruitment of metastatic colorectal cancer patients, diagnosed between 2023-2027. Recruitment activity will occur between 2024 (after CPHS approval) to 9/18/2028 (funding period). The recruitment contact will include initial mailing that includes: a) a cover letter describing the study, and inviting participation in the survey, b) a study information sheet that describes the study in more detail and includes elements of informed consent, c) a California Cancer Registry (CCR) brochure describing the role of the cancer registry and how participants are identified in the cancer registry database, d) a self-administered baseline survey, e) a self-addressed postage-paid return envelope as well as a QR code for online survey access, and f) additional survey and cover letter in Spanish or a postcard to request materials in Spanish. If participants request materials in Spanish, a mailing package with the Spanish translations of the aforementioned materials will be sent to them.
Individuals who choose to participate can either complete the paper survey and return it in the envelope provided with the return postage attached or complete online, for which QR code with link to the survey and instructions will be provided in the introductory letter. In absence of response within 2 weeks, CRGC recruitment staff will make follow-up phone calls to ensure the potential participants received the mail and to answer any questions they may have about the study. Completion of the baseline survey will constitute enrollment in the study. A second mailing will be sent to thank the participant and provide incentive as well as to request a medical release form for approval and consent to obtain medical records for additional cancer care information. Three additional follow-up surveys will be sent at 4, 8, and 12 months from initial survey mailed date to those who enrolled in the study and if they respond to these surveys, another mail will be sent with thank you letter and a gift card. At the end of the baseline survey, if participants agree to be contacted via text or email for follow-up surveys, these options will be used. All additional materials for the follow-up surveys (surveys, follow-up letters, etc.) will be submitted via an amendment for review before use.

2. Analysis of de-identified registry data from 2023 – 2033 on eligible mCRC patients diagnosed between 2023-2027 from CRGC catchment area (see Attachment A for variable list). GU will receive this data to be used for analysis in combination with the newly collected data, including assessment of of long-term survival outcomes. For latter purpose, survival-related data for the study cohort will be updated annually for up to 12/31/2033.

3. EODA sub-study: Following completion of baseline, a subset of participants who have opted to receive electronic follow-up reminders by

providing an email address and/or phone (see Study Preferences Form) will be invited via email and/or text to enroll in the end-of-day assessments (EODA) sub-study. In case there is an insufficient number of participants who opt into electronic follow-up, we plan to contact participants who did not opt in to electronic follow-up via mail until we are able to enroll n=160 participants.
Recruitment activity for the EODA sub-study will be completed within 4 weeks of baseline. Initial outreach materials will include a) a cover letter describing the EODA sub-study, and inviting participation in EODAs, b) a study information sheet that describes the EODA sub-study in more detail and includes elements of informed consent, and c) an enrollment form asking participants about their preferences for receiving the EODA surveys. Those who complete the EODA enrollment form will receive brief (<5 minute) EODA surveys electronically via email and/or text (as preferred) every three days for a maximum period of 14 weeks.
Participants will have the option to request these electronic materials in Spanish. We will provide Spanish translations of these materials in a future amendment.

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.

4-Month Follow-up Survey	Instruments
Baseline Survey in Spanish	Instruments
Draft version of baseline survey in English	Instruments
EODA Survey	Instruments
Updated baseline survey in English 07-11-2024	Instruments
IRB protocol	Protocol
SMS/Email scripts for participants who opt into electronic reminders	Recruitment Materials

RECORDING

Will audio or video recording occur?

No

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.

Not applicable

STATE DEPARTMENT DATA/SPECIMENS

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

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

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.

Upon approval from IRB and CPHS, sample selection at CRGC will occur based on early case ascertainment (ECA) using the registry data available. In case of insufficient eligible cases identified via ECA, which involves use of processed registry data for sample selection, we plan to use rapid case ascertainment (RCA) using pathology reports to identify eligible cases. Eligible sample for recruitment will include adults of ages 18 or older from CRGC's catchment areas, who were diagnosed with metastatic colorectal cancer within 2-13 months from the date of initial contact. Furthermore, eligible individuals will include only those with pathologically confirmed diagnosis and have no prior diagnosis or simultaneously diagnosed with another cancer. Patients unable to read or speak English or Spanish as well as those who have mental or cognitive impairment will be excluded. During the recruitment period (2024 – 2028), up to 2,500 eligible patients will be identified and sent out initial mail, with a goal to enroll 900 individuals from CRGC catchment areas in the study. We aim for a diverse study population that includes adequate representation from women and minorities. No individual will be excluded on the basis of sex, gender, race, or ethnicity.

EODA sub-study: Following completion of baseline, a sub-sample of up to 400 participants who have opted to receive electronic study follow-up reminders will be identified to receive brief (<5 minute) end-of-day-assessments (EODAs) through the 4-month follow-up, with the goal of enrolling n=160 participants in the EODA sub-study. In case there is an insufficient number of participants who opt into electronic contact, participants who did not opt in to electronic contact will be identified and contacted via mail until there are n=160 participants enrolled in the EODA sub-study.
This sub-sample of EODA participants will be stratified by enrollment by age at time of mCRC diagnosis (i.e. <=50 years v. >50 years) and recruitment site (NJSCR v. CRGC). Individuals eligible for EODA must also have a device (phone, tablet, computer) that is capable of accessing the internet and be willing and able to receive EODA surveys via email or text communication.

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.

California Cancer Registry

Two sets of data will be used.
1) Selection of cases for recruitment into THRIVE Study (involving patient contact)
2) Registry data on the cases selected for patient contact including sociodemographic characteristics, tumor-related, initial treatment- related, and other relevant clinical data available in the registry data.

For both datasets, death certificate variables (see attached file) will be used. Vital status will be used during sample selection process, if available, to exclude anyone who have passed away at the time of initial contact. Survival related variables will be used to assess long-term survival and determine factors predictive of better survival. We plan to apply for access to these data with VSAC.

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 - Variable list List of Variables

RATIONALE

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

A key reason for evaluating patient-reported outcomes including symptoms and function is to provide a strong evidence base to inform clinical care and to guide the next generation of interventional studies designed to improve these outcomes. There is a growing sense within the oncology research and advocacy community that accurate and comprehensive information on the health status and needs of persons with metastatic cancer is lacking. Our study results will provide novel evidence-based information on this topic and help inform and guide the design of future interventions at both the individual and health care system levels to improve health outcomes for those with metastatic cancer.

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.

A file of cases will be requested from the CCR based on diagnosis years (2023 - 2027) and cancer type (colorectal cancer). In case of insufficient eligible cases from the CCR database of processed cases, available pathology reports will be used to identify eligible individuals. No patient contact is involved.
Cases who will be contacted to enroll in the THRIVE Study will be identified based on year and month of diagnosis, age at diagnosis (18+), stage at diagnosis, county of residence at the time of diagnosis (to ensure only CRGC catchment area cases are included) and alive at the time of sample selection. For cases identified via pathology reports, physician notification will be sent to providers treating such cases prior to initial patient contact. Initial contact will be done via mailing and the mailing package will include a) a cover letter describing the study, and inviting participation in the survey, b) a study information sheet that describes the study in more detail and includes elements of informed consent, c) a California Cancer Registry (CCR) brochure describing the role of the cancer registry and how participants are identified in the cancer registry database, d) a self-administered baseline survey as well as a link and/or QR code to access the survey online using a secure platform (REDCap), e) a self-addressed postage-paid return envelope, and f) additional survey and cover letter in Spanish or a postcard to request materials in Spanish. If participants request materials in Spanish, a mailing package with the Spanish translations of the aforementioned materials will be sent to them.
Two weeks after initial mailing, if no response received, CRGC recruitment staff will make follow-up calls.

EODA sub-study: Following completion of baseline, a subset of up to 400 participants (with the goal of enrolling n=160 participants total) who have opted to receive electronic study follow-up reminders will be contacted via email and/or text to receive brief (<5 minute) end-of-day-assessments (EODAs) through the 4-month follow-up. In case there is an insufficient number of participants who opt into electronic contact, participants who did not opt in to electronic will be contacted via mail until we are able to enroll n=160 participants in the EODA sub-study. The initial contact materials will include: a) a cover letter describing the EODA sub-study, and inviting participation in EODAs, b) a study information sheet that describes the EODA sub-study in more detail and includes elements of informed consent, and c) an enrollment form asking participants about their preferences for receiving the EODA surveys. Those who complete the EODA enrollment form will receive brief (<5 minute) EODA surveys electronically via email and/or

text (as preferred) every three days for a maximum period of 14 weeks. Participants will have the option to request these electronic materials in Spanish. We will provide Spanish translations of these materials in a future amendment.

Attach copies of all recruitment materials.

EODA Cover Letter	Recruitment Materials
EODA Enrollment Form	Recruitment Materials
EODA Study Information Sheet	Recruitment Materials
EODA Survey	Recruitment Materials
Physician Notification Form for RCA	Recruitment Materials
Physician Notification Letter for RCA	Recruitment Materials
Recruitment materials	Recruitment Materials
Recruitment materials	Recruitment Materials
Recruitment materials	Recruitment Materials
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Recruitment Materials in Spanish	Recruitment Materials
Recruitment Materials in Spanish	Recruitment Materials

Recruitment Materials in Spanish	Recruitment Materials
SMS/Email scripts for participants who opt into electronic reminders	Recruitment Materials
Study Brochure Text	Recruitment Materials

Deleted Attachments: 2 (Most Recent: 4-Month Follow-up Survey on 10/31/2024 5:12 PM ET)

SCREENING

Will subjects be screened prior to entry into the research?

No

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
Participants who complete the baseline survey will be provided a $40 gift card, and a $15 gift card will be provided for each follow-up survey completed. A $15 gift card incentive will be provided for completed medical record release forms.

Participants who complete end-of-day assessments (EODAs) will receive $5 per completed EODA survey for up to 32 total surveys. Incentive payments will be made via gift card in monthly installments.

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.

Participant involvement will span the course of one year from the time of baseline survey completion. Participants will be asked to complete a baseline survey and participants who complete the baseline survey will be considered enrolled in the study. The enrolled participants will then receive 3 additional surveys approximately at 4, 8 and 12 months after the completion of the baseline survey. A small subset of participants will be sent a request to allow access to their medical records for additional their cancer care related clinical information as well as the names and addresses of their cancer care providers. This request will be included in the mailing packet with gift card and thank you letter for completing the baseline survey. The baseline survey is expected to take about 40 minutes, and each follow-up survey is expected to take approximately 25 minutes. Total time commitments is estimated at approximately 2 to 2.5 hours (survey only vs both survey and medical record release form).

Following completion of baseline, a small subset of enrolled participants who have opted to receive end-of-day assessments (EODAs) will additionally receive brief (<5 minutes) electronic EODA surveys every three days for a maximum period of 14 weeks, for a total time commitment of up to 2.6 hours. EODA participants will be able to select a preferred time between 5pm and 10pm in which they will receive EODA surveys.

Risks and Benefits

RISK DESCRIPTION

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

There are minimal risks involved in being a subject in this study. This prospective observational study does not involve administration of any treatment or other medical intervention. There is a minimal psychological risk that participants may be made uncomfortable or emotional by answering questions related to their cancer and related symptoms. A second risk for this study is the potential breach of confidentiality. This could be a release of the clinical or other potentially sensitive data collected as part of this study. The risk of unauthorized or accidental release of such data is extremely unlikely given the precautions that will be taken to minimize such an event.

MEDICAL SERVICE RISKS

Describe how medical services will be provided if subjects suffer adverse mental or physical effects as result of research activity. If no services provided, state that clearly.

We will use several strategies to mitigate and address the risk of participant distress. In the Study Information Sheet and/or survey instructions, participants will be reminded that they may take a break from the surveys at any time, may refuse to answer questions at their discretion, may stop their study participation at any time, and are encouraged to discuss any significant symptoms with their healthcare team. In the study cover letter, participants will be provided with the registry site Principal Investigator's contact information; participants will be encouraged to call if any questions or concerns arise, and a list of mental health resources will be provided upon request (e.g., 988 Lifeline, SAMHSA's National Helpline, Cancer Support Community). We do not anticipate that participants will express thoughts of harming themselves or others in the context of this study, because the surveys are not assessing such thoughts. In the unlikely event that thoughts of physical harm are expressed during a phone call with registry staff, the participant will be referred to an appropriate resource (e.g., primary physician, crisis helplines, local emergency services).

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.

Cohort: The method selected (i.e., survey completion and medical record abstraction) are considered to have the lowest risk. Furthermore, all data collected will be de-identified by CRGC staff before using for data analysis so study findings cannot be traced back to participants within the analytic environment.
Datafile: Only possible risk is loss of confidentiality. De-identified research file will be used for analysis to minimize this risk.

BENEFITS

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

While there is no direct benefit to the patients with cancer selected for this study, the information from this study may be useful in managing cancer related symptoms for future persons living with mCRC, and possibly those with other types of advanced or incurable cancers. Accurately and comprehensively documenting the trajectory of patient-reported outcomes for persons with mCRC is essential for informing new policies and clinical programs aimed at helping patients and their clinicians better manage the adverse effects of cancer therapies.

JUSTIFICATION OF RISKS

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

There is limited information on patient report outcomes (PROs) for patients with metastatic colorectal cancer. This study will systematically document such PROs, which will inform the development of effective interventions to manage metastatic colorectal cancer and improve survival outcomes in future. Thus, benefits of this study far outweigh the minimal risk it poses.

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
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 NIH's data security and confidentiality as well as CITI program's Human Subject Research training and sign confidentiality pledge (Appendix 2).

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 Public Health Institute 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.

Departmental Letter of Support Department Letter of Support

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

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

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

All data will be kept on secure servers and not released to any unauthorized person or entity. Drs. Shrestha and Potosky will assure that they will not release data for any other purpose by signing the 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 include individual's names or allow for identification of an individual. All results will be presented only in aggregated form.

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 carefully assessed the number of cases required to meet the study's goals and have based the number of years of accrual on historical incidence rates for the population of interest.

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.

Social security numbers will only be used to trace the lost subjects.

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.

Cells with under 11 cases will be suppressed in all publications, per the DHCS guidelines.

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 de-identified registry data set will be linked to new data collected through baseline and follow-up surveys. For a subset of participants, additional data abstracted from their medical records will also be linked to the de-identified registry data. The linkage will be done using a crosswalk of patient id and study id prepared prior to the linkage (after sample selection for recruitment is done) to ensure de-identification is maintained for both all data sets involved in linkage and the final linked data set.

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 Letter PHI - THRIVE (02-07-2024) signed.pdf	Data Security Letter
Datasecurity_letterCPHS_Potosky_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.
Personally identifiable information, which include patient name, address, telephone numbers, and social security numbers will be excluded from the registry data prepared for analysis. Unique numeric patient id will be used to differentiate records for different individuals.

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.

SRFax will be used to send and receive faxes. SRFax is HIPAA compliant and PHI has a Business Associate Agreement (BAA) with them. The incoming faxes must be downloaded from SRFax servers and are deleted after 30 days.

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 would be sealed and protected. There will be no mailing of 500 or more individually identifiable records of PID in a single package.

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 never be left unattended in cars or other unsecured locations. Any study data stored on laptop computers will be encrypted.

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 PHI 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 PHI 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.

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.

Password protected computerized tracing databases containing case-identifying information will be accessible only to eligible study staff via password secured computers.

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

FIPS 140-2 COMPLIANCE: LAPTOPS

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

Yes, see above.

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 with PID will be encrypted.

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, security patches are applied as they become available. Generally, they are applied within 30 days of release, on a monthly bases. Urgent patches will be applied as they are made available.

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 password controls are in place.

ELECTRONIC SECURITY CONTROLS

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

Yes, sufficient system security controls are in place.

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 for recruitment part of the study.
When requesting medical records from cancer care providers, we will use GoAnywhere to transmit electronic data securely. GoAnywhere transmissions are encrypted and are compliant with FIPS 140-2.

INTERNET ACCESSIBILITY

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

No they 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. We will follow NIST SP 800-88 Guidelines for Media Sanitation for this purpose.

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.

For the survey component of the study, we request a waiver of signed documented consent. Eligible candidates will receive an information sheet that includes the elements of an informed consent along with the survey. They can choose to participate by returning the completed survey or not return it if they wish not to participate.
We will obtain a signed medical record release form that would give us permission to contact their providers to access relevant medical records for the study.

For the EODA component of the study, a small subset of enrolled participants who are identified as eligible will receive a) a study information sheet that includes elements of informed consent, and b) an EODA enrollment form. Eligible candidates can choose to participate in the EODA sub-study by completing the EODA enrollment form or not respond if they wish not to participate.

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.

EODA Enrollment Form	Consent Form
EODA Study Information Sheet	Consent Form
Medical record release form	Consent Form
Medical Record Release Form (Spanish)	Consent Form
Study information sheet with elements of informed consent	Consent Form
Study Information Sheet with elements of informed consent (Spanish)	Consent Form

TRANSLATED DOCUMENTS

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

Note that this project cannot be approved until all Spanish language documents are submitted and reviewed.

12/02/2024 • Catherine Hess, PhD

Placeholder for non-English version of study information sheet	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.

M. Gutierrez CV.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?

Yes

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

HIPAA WAIVER

Are you requesting a waiver or alteration of HIPAA authorization?

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

No

HIPAA AUTHORIZATION FORM

Upload a copy of the HIPAA Authorization form(s) or the documentation of the approval of a waiver/alteration from another IRB.

HIPAA Medical Record Release Form (Spanish)	HIPAA Documents
HIPPAA Medical Record Release form	HIPAA Documents

Amendment Changes

List the pages and questions that have been changed.

In "Project Details > Study Procedures," we have:

- Added procedural details about the EODA sub-component.
- Attached EODA materials: EODA Survey.
- Attached study materials as mentioned in our initial application: (1) 4-Month Follow-up Survey, and (2) Text/Email Message Template.

In "Study Population > Population Description," we have:

- Added information about eligibility criteria for the EODA sub-component of the study.
- Added information about the use of rapid case ascertainment, using pathology reports to identify eligible individuals.

In "Study Population > Recruitment Details," we have:

- Added information about recruitment procedures for the EODA sub-study.
- Attached EODA contact materials: (1) EODA Cover Letter, (2) EODA Study Information Sheet, (3) EODA Enrollment Form, and (4) EODA Survey.
- Added information about the use of rapid case ascertainment, using pathology reports to identify eligible individuals.
- Attached physician notification materials used for RCA cases: (1) Physician notification letter, and (2) Physician notification form.

In "Study Population > Compensation," we have:

- Added information about additional compensation for individuals participating in the EODA sub-component.

In "Study Population > Study Duration," we have:

- Added information about the time commitment for individuals participating in the EODA sub-module.

In "Informed Consent Procedures > Informed Consent Procedures," we have:

- Added details about additional informed consent materials used to enroll individuals in the EODA sub-component of the study.
- Attached the informed consent materials for EODA to this section: (1) EODA Study Information Sheet, and (2) EODA Enrollment Form.

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 for recruitment efforts Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

CPHS Cover Letter Signed.pdf Cover Letter

In order for the PI to review and sign this form, you will need to click "Next" and on the next page, click "Submit." At that point the PI will receive notification that will need to review the application and if they request changes, they will return the form to you and you will receive an email notification.