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

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

December 2024 cycle.
----------New HSC Project----------

A LOS from CCR is attached.
A DSL from Medical University of South Carolina (MUSC) is attached.

11/06/2024 • Sussan Atifeh • Internal

Researchers from UCSF have submitted this application to request CPHS approval (as the IRB of record for an entire multi-site study led by UCSF and involving NYU Langone Health) for a project, funded by the CDC, seeks CPHS.
• The project is aimed to evaluate patient perspectives on prostate cancer pathology terms through focus groups, interviews, and surveys, with data managed and housed at UCSF.
• Researchers have requested PII from CCR to identify eligible participants diagnosed with low-grade prostate cancer (GG1) in California.
• A Letter of Support (LOS) from CCR is attached but it does not follow the requested format specified on the CPHS website.
•This project wants to rely on CPHS as the overseeing IRB of record for this multi-site project and (after the approval of the study by CPHS) they plan to submit amendment by attaching the fully signed reliance agreement form(s) (signed by their perspective IRBs and CPHS Chair) to document this agreement in the project application.
• A DSL from UCSF is attached.

Fund:
This project is federally funded (by CDC)

Human Subjects: The study involves direct contacts with human subjects via recruitment from the CCR, focus groups, and interviews, with a primary focus on Black and Hispanic men, representing California's racial and socioeconomic diversity.

1. Qualitative Focus Groups: Conducted by NYU Langone, with diverse patients discussing pathology report terminology, particularly around “cancer” vs. “neoplasm/lesion.”
2. One-on-One Interviews: Gather in-depth input on patient preferences for terminology and care options, which will inform a Discrete Choice Experiment (DCE).
3. Quantitative Survey: A DCE survey with 525 participants to explore how terminology and diagnosis labels impact patients’ perceptions of treatment options.
Requested State Data:
This project has requested PII from the California Cancer Registry (CCR). The researchers have requested recruitment information from the CCR to identify eligible participants diagnosed with low-grade prostate cancer (GG1) in California.

NYU Langone Health Involvement in Project
NYU Langone in this project primarily involves conducting virtual focus groups. Researchers from NYU will facilitate these groups on the secure UCSF Zoom platform. They will work alongside UCSF to engage eligible patients from CCR listings in discussions about prostate cancer pathology terminology and patient-centered reporting.

11/08/2024 • Sussan Atifeh • Internal

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

New Contact Form

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Please select Medical University of South Carolina (MUSC) as the PI's institution from the dropdown menu. Thanks.

11/07/2024 • Sussan Atifeh • *Not* Internal • Resolved

Evan Graboyes, MD, MPH

Email: graboyes@musc.edu **Business:** (843) 792-8299

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

Medical University of South Carolina (MUSC)

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

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

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

South Carolina

Attach a copy of the PI's Curriculum Vitae.

Dr. Evan Graboyes Biosketch PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

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

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

Ashish Deshmukh, PhD, MPH

Email: deshmukha@musc.edu **Business:** (843) 792-6955

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

Dr. Ashish Deshmukh Biosketch Co-PI Curriculum Vitae

ADMINISTRATIVE CONTACT

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

Ella Starr, MPH, BS

Email: ejs300@musc.edu **Business:** (843) 496-4020

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

*The RO **cannot** be the same person as the PI or Co-PI. The RO must have supervisory authority, in the administrative structure of the institution, over the PI.*

David Azbill, PhD

Email: azbilld@musc.edu **Business:** (843) 792-3828

OTHER RESEARCH STAFF

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

Will the PI and co-PI be the only individuals involved in this study with access to the information received from CCR? That is, all activities described in this application, including recruitment and analyses, will be undertaken by the PI and co-PI only? If other individuals will have access to the data please list them here. If they are not listed an amendment will be required to add anyone with data access in the future.

11/15/2024 • Laura Lund, MA • *Not* Internal

The following individuals are listed in the budget but not listed here. If they will have access to the CCR data please include them as research staff.Kalyani Sonawane
Bhishamjeet Chera
Elizabeth Hill
Haluk Damgacioglu
Gerald Silvestri
Taylor McLeod
Ketki Borse
TBN
Alexis Nuzzo

11/15/2024 • Laura Lund, MA • *Not* Internal

Repeat this action for all other research staff not previously provided on this screen that should receive notifications about this project. If there are no additional research staff, skip this question.

Elizabeth Hill, PhD
Email: hille@musc.edu **Business:** (843) 876-1115

Ella Starr, MPH, BS
Email: ejs300@musc.edu **Business:** (843) 496-4020

Abigail Drake, MPH
Email: abd300@musc.edu **Business:** (843) 876-9844

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

False

Project Information

SUBMITTER

Application completed by:

Ella Starr, MPH, BS

Email: ejs300@musc.edu **Business:** (843) 496-4020

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).

Priorities, Preferences, And Tradeoffs Among Older Adults With Oropharyngeal Cancer

PROJECT SITE

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

If the main site for this project is Medical University of South Carolina (MUSC), please select it from the dropdown menu.

The main site(s) refer to the institution(s) responsible for the primary storage, receipt, and management of study data, as well as ensuring data security and compliance with relevant regulations. This includes overseeing access controls, data encryption, privacy safeguards, and typically housing and managing the servers through which the data is processed.

11/07/2024 • Sussan Atifeh • *Not* Internal • Resolved

Medical University of South Carolina (MUSC)

STUDY PROCEDURES

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

If you have requested any state data from any state departments, please select "Data Registry" as well.

Also, please attach all lists of requested variables (using descriptive names) by attaching the formal data dictionaries in the "DATABASE DETAILS" section.
In the attached list(s) you need to provide a brief explanation to justify requesting each variable and to show the use of the variables. Thanks,

11/07/2024 • Sussan Atifeh • *Not* Internal • Resolved

Data Registry
Recruitment-Participant
Surveys

TYPE OF RESEARCH REQUEST

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

Please de-select "Common Rule only" and keep "Common rule/human subjects".

CPHS is mandated to conduct an Information Practices Act (IPA) review for your project (since you have requested state personally identifiable information to conduct this research) to ensure compliance with privacy and security requirements for state-held data. Please select "Information Practices Act" as well as "Common rule/Human subjects."

Please note you might be requested by the reviewing committee members to select a different option in this section at a later stage which in this case you will be notified by them.

11/07/2024 • Sussan Atifeh • *Not* Internal • Resolved

*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)*

SB-13 (Information Practices Act)
Common rule/Human subjects

PROJECT TYPE DETAILS

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

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

Minimal Risk
Consent form

VULNERABLE POPULATIONS

Indicate which vulnerable populations, if any, will be involved with this research. Check all that apply.

If vulnerable populations are not part of the research, choose "Not applicable."
Note regarding minors: in the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted.

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.

Since your project has human subjects' contacts components, and it is not eligible for an expedited review, please select "Not applicable."

11/07/2024 • Sussan Atifeh • *Not* Internal • Resolved

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.

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard. Please select 12/6/24 or a date following this date within a few weeks.

11/07/2024 • Sussan Atifeh • *Not* Internal • Resolved

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

12/06/2024

ANTICIPATED PROJECT END DATE

11/30/2029

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.

Data to guide optimal treatment and preference-concordant shared decision-making among older adults with HPV-related oropharyngeal cancer (OPC) are lacking. First, several recently completed and ongoing trials evaluated treatment deintensification among patients with OPC. However, older adults were severely underrepresented, none were designed specifically for older adults, and none considered comorbidity burden in outcomes evaluation. Furthermore, due to challenges in conducting trials in these patients (e.g., exclusion criteria for comorbid conditions, physicians' perceptions, treatment tolerability), it is unlikely that randomized clinical trials (RCTs) specifically evaluating treatment of OPC among older adults will be conducted in the future. Second, although the tradeoff between treatment priorities and preferences for oncologic (e.g., survival) and non-oncologic (e.g., swallowing) outcomes is crucial to guide treatment, this tradeoff has never been rigorously investigated in the context of aging or comorbidity due to limitations of prior studies such as small sample size, heterogeneous population, and lack of quantification. Due to the lack of integrated, high-quality data on treatment outcomes (AEs, oncologic outcomes, QOL) and preferences, OPC treatment among older adults is currently guided by inappropriate extrapolation of data from studies in younger patients, preventing clinicians and patients from making data-driven, preference-concordant decisions. The purpose of this study is to understand the priorities and preferences of patients with HPV-OPC in relation to aging and overall quality of life. This project will use the CCR data for participant recruitment and to collect demographic and clinical date from participants. The CCR was selected for patient contact and recruitment because CA has the highest overall burden of OPC in the US. The project will take place at the Medical University of South Carolina.

MAJOR RESEARCH QUESTION

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

Primary Objective: To characterize the impact of aging and multimorbidity on treatment priorities and preferences among patients with human papillomavirus (HPV)-related oropharyngeal cancer (OPC).

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

Please also clarify if this project has been received a Common Rule review from the IRB at the Medical University of South Carolina (MUSC)? Thanks.

11/07/2024 • Sussan Atifeh • *Not* Internal • Resolved

Please provide more details about procedures for patient recruitment.

CCR will provide your study team with a list of 'eligible participants'? To confirm, CCR will be able to screen and provide only potential participants who are
• Age >18 years
• History of HPV-related OPC
• Undergoing or completed treatment for HPV OPC within 5 years of study accrual
• Speaks English

You state that: Once the list of interested, eligible patients is obtained along with their contact information, we will call patients to recruit them for the study using approved methods.

--How will you know that they are 'interested'? Will CCR be contacting individuals about
this study prior to providing you with the list of names and contact information?
--What does 'using approved methods' mean? All contact protocols should be described
here in this application for approval.

11/15/2024 • Laura Lund, MA • *Not* Internal

You state that you will call potential participants to recruit them. Please provide scripts for all recruitment phone calls.

What is the protocol for calling potential participants? How

many phone calls will you make?

11/15/2024 • Laura Lund, MA • *Not* Internal

Please provide the full script you will use for the video teleconference session.

11/15/2024 • Laura Lund, MA • *Not* Internal

In the attached document entitled "Protocol Letterhead" you state:As in prior studies, we will contact approved patients by email, telephone, and/or text message to invite them to participate in the research study.

Please describe your recruitment procedures for this study in detail here in the procedures section. How many emails, telephone calls, and text messages will potential participants receive? Previously in this section you stated that you would be calling potential participants, this supplemental document seems to indicate three recruitment modalities. Please clarify.

Please provide all telephone, email, and text scripts that you will use during recruitment.

11/15/2024 • Laura Lund, MA • *Not* Internal

The consent process described in the supplemental document entitled "Protocol Letterhead" seems confusing and inconsistent with the procedures described here.

You state: After determination of study eligibility, participants will complete remote e-consent with a study team member.

--At what point in the recruitment process will this determination of eligibility and
consenting take place? Elsewhere in the protocol you appear to be saying that CCR will screen for eligibility and provide only eligible names to you. Is there additional screening for eligibility? When would that happen? You mentioned recruiting via email and text--are there instructions in these emails and texts for participants to call a study team member to go through the consenting process?

You state that participants will receive a link to an e-consent form. Is this via text and/or email? When do they get this

link--while they are on a recruitment call with a staff member, after the call, do they schedule a time with the staff member to go over the consent form?

In the supplemental document you state: Since recruitment is occurring via online patient support pages and email listservs, all potential participants will have internet access and thus access to the e-consent form.

--These are not the recruitment procedures you have described here. Please clarify.
Based on your the procedures you have described it is possible that not every participant
will have access to the internet.

11/15/2024 • Laura Lund, MA • *Not* Internal

The study procedures state that the video teleconference will not be recorded. The supplemental study documentation states that there will be audio and video recording of these sessions. Please clarify.

11/15/2024 • Laura Lund, MA • *Not* Internal

Please provide the actual instrument in its final form that will be administered to participants during the video teleconference, including all introductory and transitional scripts.

11/15/2024 • Laura Lund, MA • *Not* Internal

CPHS is required to ensure that minimum data necessary to complete the study is released. Your request for CCR variables includes what appear to be controlling variables (smoking) as well as demographic characteristics (marital status, zip code of residence, race, etc.). Please describe your analysis plan for the requested variables in enough detail to justify their inclusion in the study.

11/15/2024 • Laura Lund, MA • *Not* Internal

Please provide more detail about how PII will be handled. Will all contact information (name, address, telephone number, etc.) be removed and destroyed after enrollment in the study? Will you retain any PII (such as address or specific dates) in the final analysis database?

11/15/2024 • Laura Lund, MA • *Not* Internal

Clinical, demographic, and contact information of eligible participants will be obtained from the CA cancer registry according to their data collection and patient recruitment protocols. Once the list of eligible patients is obtained along with their contact information, we will call patients to recruit them for the study using the approved phone script. Patients will be called up to five times.

After determination of study eligibility and recruitment, participants will complete remote e-consent with a study team member. Participants will receive a link to an e-consent form, available via REDCap, that they can review and sign. Review of the consent form will be paired with a phone call with a research team member to ensure that all questions are answered prior to enrollment. A copy of the signed consent form will be provided to the subject by their preferred email after they are fully enrolled.

Participation in the study will be conducted over a single, 30-minute video teleconference session. This teleconference session will not be recorded. Participants will complete the following procedures solely as part of the research study:

1. Information about participant background and cancer history will be obtained from state cancer registries.

2. Participants will complete the 12 item Chicago HNC Priority Scale. This 12-item scale is a validated tool for assessing priorities for treatment outcomes among patients with HNC. Respondents rank the relative importance of 12 treatment outcomes (e.g., survival, being able to swallow food and liquids) on an ordinal scale from 1 to 12 with 1 representing the top treatment priority.

3. Participants will complete the utility assessment and preference for toxicity avoidance vs survival via the Standard Gamble (SG). The SG is the gold standard approach to measure cardinal preferences for states of health and utility. In brief, participants will be asked to choose between their current health state and a hypothetical treatment that has a probability (1-P) of leading to a life with perfect health and probability P of immediate death to understand their health utility.

Trained study staff will determine treatment priorities via the Chicago HNC Priority Scale and utilities and preferences for toxicity avoidance vs survival via the Standard Gamble (SG). This study does not involve determining treatment options for the participants enrolled. All study procedures will be conducted remotely via video teleconference platform.

Our target n for the California portion of the study is 50 participants. To achieve that number, we are requesting 500 cases from CCR. We are requesting data from the years of 2019-2023.

Analysis Plan: We will comprehensively characterize our clinical sample with relevant demographic (e.g., age, sex, race, etc), clinical (e.g., comorbidities,

smoking status), oncologic characteristics and social determinants of health (based on neighborhood level geocoded zip code information). Univariate associations between utility scores and continuous variables will be evaluated using scatterplots and correlations. Associations with categorical variables will be evaluated using Wilcoxon rank-sum or Kruskal-Wallis tests for two or multi-group comparisons, respectively. Multivariable linear regression will determine associations between utility score and age (considered in separate models as continuous or categorical, <65 vs >65 years), with adjustment for comorbidities, race, time since treatment, and treatment modality. In models with age as a continuous variable, we will evaluate the functional form of age and consider transformations to accommodate non-linearity. Our goal is to understand both the covariate-adjusted relationship between age and utility score to test our hypothesis.

We justify the inclusion of patients aged 18-64 years in addition to older adults for two reasons. First, inclusion of younger adults is necessary to test our hypothesis that increasing age is associated with a greater preference for avoiding toxicity over survival preservation. Second, including younger adults will help generate utilities in association with age. We justify the inclusion of patients currently undergoing treatment and post-treatment survivors because this approach ensures that we comprehensively capture the experiences of acute and chronic toxicity and their impact on treatment preference. We justify the inclusion of controlling variables (such as smoking status) to allow a comprehensive sample of patients with HPV-related OPC.

This project has been received a Common Rule review from the IRB at the Medical University of South Carolina (MUSC).

PII (name, address, telephone number, specific dates) will be removed and destroyed after study enrollment. The study database will only contain de-identified information.

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.

HNC Prioritization Scale.docx	Questionnaires
The Standard Gamble Script 2024.09.18.pdf	Questionnaires

Deleted Attachments: 1 (Most Recent: Protocol Letterhead on 11/15/2024 3:54 PM ET)

RECORDING

Will audio or video recording occur?

The supplemental protocol document you submitted states that both audio and video recording will occur. Please clarify.

11/15/2024 • Laura Lund, MA • *Not* Internal

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.

Is CDPH providing research staff, funding and patients from State mental hospitals for this project? if not, please select "Not applicable."
Thanks,

11/07/2024 • Sussan Atifeh • *Not* Internal • Resolved

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 (CCR)

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.

Please clarify in the procedures section--
Your target n for the California portion of the study is 50?
How many cases are you requesting from the CCR to achieve your n of 50?
What years of data are you requesting?

11/15/2024 • Laura Lund, MA • *Not* Internal

The study participants will be all adults over the age of 18 with a history of HPV-related oropharyngeal cancer. Participants will be of all ages (over 18 years), and they will not be excluded based on sex, ethnicity, and race. All races, all sexes/genders, and all ethnicities will be recruited. The requested number of participants from the CCR is 50 participants. To achieve that number, we are requesting 500 cases from CCR.

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 database to be used for recruitment and data collection is the California Cancer Registry (CCR). We will be collecting data on patient demographics, patient clinical information, and patient contact information. The time period being requested is 12/01/2019 – present (inclusive of up to 2024). The specific variables and justifications are listed in the attachment below.

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.

Final_Approved_List of Requested CCR Variables.2024.10.28.xlsx	List of Variables
SCCCR Database List of Variables.2024.11.08.pdf	List of Variables

Deleted Attachments: 1 (Most Recent: List of Requested CCR Variables.2024.09.13.xlsx on 10/29/2024 9:37 AM ET)

RATIONALE

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

Greater comorbidity burden: Aging is the most potent risk factor for multimorbidity, with >80% of older adults with OPC having >1 comorbid condition and >50% having =2. Among patients with OPC, multimorbidity is strongly associated with increased treatment toxicity and worse survival. Notably, persons with >3 comorbidities have a 13-fold increase in all-cause mortality, implying that competing causes of death may attenuate treatment benefits. Indeed, multiple meta-analyses showed that the risk of other-cause mortality increases with increasing age (15% in <50 years to >40% among =65 years) among patients with OPC.

Narrower therapeutic index: Older adults with OPC have a reduced therapeutic index (i.e., the ratio of the dose of drug that causes AEs to the dose that leads to the desired effect). As a result, they are at an increased risk of SAEs, reduced probability of tumor control, decreased functional status, and impaired QOL.

Altered treatment priorities and preferences: A few studies suggest that older adults with head and neck cancer (HNC) may differ from younger patients in terms of their treatment priorities and preferences for balancing survival with toxicity. One small study (N=51; n=23 age =60 years) reported that 31% of patients were willing to compromise 0%-5% survival benefit to reduce treatment toxicity. Another study of patients with HNC (N=150 [81 with OPC]); median age 60 years) showed that increasing age was associated with increased prioritization of improving QOL over survival. To inform optimal treatment of older adults with OPC, careful consideration should be given to comorbidity burden, therapeutic window, and priorities and preferences unique to this patient population. However, younger participants will also be recruited in order to have a significant sample.

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.)?

Please see comments in the procedures section with questions regarding recruitment procedures.

11/15/2024 • Laura Lund, MA • *Not* Internal

Is this the final version of the consent form for this study?

--The section on MUSC medical records seems not applicable to participants recruited in CA.
--The form states that there will be a $50 reimbursement. Please describe this in the procedures section.
--The form states that participants will be given the gift card 'at the beginning of the study'. What does this mean? After informed consent but prior to the video teleconference? Please clarify.
--What does 'each time you receive payment for participation in this study' mean? Your procedures state that individuals will only participate in one 30 minute video teleconference.
--What does it mean 'as part of this research study, your study doctor and his/her research team will keep records of your participation in this study'? Your procedures do not describe assigning a study doctor to participants. Please clarify.
--You tell participants that MUSC may use or release information from the medical record, physical exams, lab tests, etc. Further, you go on to state that the research team will release health information to conduct this study. None of this has been described in the study procedures. The study procedures describe using only demographic and cancer-related information obtained from the CCR database and self-reported information obtained via interview. If you intend to use information from the medical record in the study please describe this in the procedures. A separate HIPAA authorization form will be necessary if this is the case. Please clarify.

11/15/2024 • Laura Lund, MA • *Not* Internal

It has been stated above that researchers are requesting that CPHS act as the sole IRB for this study. The consent form should state that CPHS is the appropriate contact, not MUSC IRB.

11/15/2024 • Laura Lund, MA • *Not* Internal

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

Registry-based recruitment: We carefully selected three registry partners (South Carolina [SC], Kentucky [KY], and California [CA]) to recruit OPC survivors for this project. These state registries, which provide population-representative samples from each region, were selected because (1) SC has the highest burden of OPC burden among Black men in the US, (2) KY has the highest incidence of OPC in the US, and (3) CA has the highest overall burden of OPC in the US.

Clinical, demographic, and contact information of eligible participants will be obtained from the CA cancer registry according to their data collection and patient recruitment protocols. Once the list of eligible patients is obtained along with their contact information, we will call patients to recruit them for the study using the approved phone script. Patients will be called up to five times.

After determination of study eligibility and recruitment, participants will complete remote e-consent with a study team member. Participants will receive a link to an e-consent form, available via REDCap, that they can review and sign. Review of the consent form will be paired with a phone call with a research team member to ensure that all questions are answered prior to enrollment. A copy of the signed consent form will be provided to the subject by their preferred email.

Attach copies of all recruitment materials.

TRADEOFFS Stamped ICF_2024.09.30.docx Recruitment Materials

Deleted Attachments: 1 (Most Recent: TRADEOFFS ICF.IRB_edits.2024.09.19_EMG.docx on 10/01/2024 1:34 PM ET)

SCREENING

Will subjects be screened prior to entry into the research?

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.
Inclusion Criteria
• Age >18 years
• History of HPV-related OPC
• Undergoing or completed treatment for HPV OPC within 5 years of study accrual
• Speaks English

Exclusion Criteria
• Deceased
• Received only palliative intent therapy

COMPENSATION

Will subjects be compensated for participating in the study?

Please clarify what you mean by 'at the beginning of the study'.

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Yes

Compensation type
Gift card

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
Participants will be paid $50 for participation in this study. Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card, and the participant may use the card to purchase goods or services everywhere Debit MasterCard is accepted. Participants will be given a ClinCard at the beginning of the study.

STUDY DURATION

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

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

This is a 3-year study. Participation in the study will be conducted over a single, 30-minute video teleconference session. The total approximate time commitment for participants is 30 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.

There are no physical risks to study participants. There is a possibility for psychological/emotional risk due to sensitive subject matter. Some questions the researchers may ask may be upsetting or uncomfortable for participants. There is a risk of loss of confidentiality due to participation in the study.

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.

We are collecting data on priorities and preferences from HPV-OPC patients, and therefore qualitative data is being collected through a 30-minute video conferencing session. Therefore, less risky methods are not being used.

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 will be no direct benefit to subjects from participating in this study. It is hoped that the information gathered from the participants will be used to improve preference-concordant shared decision-making and outcomes, particularly quality of life, among older adults with HPV-related OPC in the future.

JUSTIFICATION OF RISKS

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

Although there are no direct benefits to study subjects for participation, there are also no physical risks to the study subjects and very minimal confidentiality and emotional/social risks to the subjects. The information gathered from the study subjects will be used to improve preference-concordant shared decision-making and outcomes, particularly quality of life, among older adults with HPV-related OPC for the future. The participants will not be directly benefitting themselves, but they will be benefitting future OPC patients. Therefore, the study risks are reasonable.

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

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

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

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

HIPAA IDENTIFIERS

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

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

TRAINING PROCEDURES

Describe the procedures for training all research staff who have access to PID on privacy and security. Indicate if staff are required to sign a confidentiality statement related to general use, security, and privacy.

> Only the PI and co-PI have been listed as having access to the data. The comment here suggests that there are other research staff. Please list all persons with access to the data in the 'research staff' section of the protocol.
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All research staff are required to take CITI Training courses in Research with Human Subjects. Once they pass these trainings, they are granted access to PID. The MUSC IRB also oversees all research staff associated with this project.

STAFF VETTING PROCEDURES

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

MUSC research staff go through background checks before they are hired and given access to PID. They are then required to take CITI Training courses in Research with Human Subjects. Once they pass these trainings, they are granted access to PID.

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_Graboyes, E.docx.pdf	Department Letter of Support
LOS_CA Registry.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.

To help ensure and protect the privacy of participants and the confidentiality of research data for the study, we will assign a unique study ID number to each subject's information in place of his/her name and will label data collection forms with the ID number. All electronic files will be stored appropriately using password protection. Only the study team members will have access to study records. Prior to and during the study, development of – and security oversight for – the electronic database for this study will be performed by study personnel using REDCap, a secure, web-based MUSC Information Technology and Institutional Review Board-approved application to support data capture.

The data entry management system will be accessed and housed at MUSC. Data system security will be ensured by implementing multiple layered firewalls and a network intrusion prevention system for identifying and blocking malicious network activity in real-time. An electronic study log linking patient names with study ID numbers will be kept on a secure server at MUSC, and access to this log will be limited to study personnel.

CONFIDENTIALITY OF PUBLISHED DATA

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

To help ensure and protect the privacy of participants and the confidentiality of research data for the study, we will assign a unique study ID number to each subject's information in place of his/her name and will label data collection forms with the ID number. All electronic files will be stored appropriately using password protection. Only the study team members will have access to study records. No PID will be published without the use of the study ID number.

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?

Please see earlier comment regarding justification for demographic and other variables in the procedures section. CPHS is required to evaluate minimum data necessary for release of data. Insufficient information has been provided to approve all of the data fields requested.

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Human papillomavirus-associated oropharyngeal cancer (OPC) is one of the fastest rising causes of cancer incidence (3%/year) in the US, with a pronounced increase (=4%/year) among older adults (=65 years). The OPC burden is projected to double (>30,000 new cases annually) over the next few decades, with >60% of new cases occurring in patients aged =65 years. Although standard of care treatment for OPC results in excellent survival, it can cause devastating chronic toxicity and impaired long-term quality of life (QOL). Due to their comorbidity burden and narrow therapeutic index, older adults with OPC are more susceptible to treatment-related adverse events (AEs), suffer from worse QOL, and have an increased mortality risk from competing events. In addition, patient preferences regarding the tradeoff between survival and treatment toxicity, data that are critical to guide preference-concordant shared decision-making, have not been fully characterized in this population.

The variables being requested (patient contact information, clinical information, demographic information) will be used to contact and recruit eligible patients, provide informed consent to participants, confirm eligibility for the study, and comprehensively categorize the patient sample. We will comprehensively characterize our clinical sample with relevant demographic (e.g., age, sex, race, etc), clinical (e.g., comorbidities, smoking status), oncologic characteristics and social determinants of health (based on neighborhood level geocoded zip code information).

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 to data is limited to only those part of the study research staff who will implement and evaluate the research.

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

Describe appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

Please provide information on how you will protect information in the case of small cell sizes when reporting output in tabular format. Is there a threshold value?

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N/A

LINKAGES

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

No

DESTRUCTION OF PID VERIFICATION

Indicate that you will provide CPHS with a letter certifying that PID has been destroyed and/or returned to the data source once research is concluded.

Yes

DATA SECURITY LETTER

Upload a certification/statement from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.

- *Data security letters cannot be signed by the Principal Investigator or Responsible Official.*
- *The data security letter must be on your institution's letterhead.*
- *Example of data security letter*

Data-Security-Requirement-Letter_CPHS.2024.09.23-AKH_Signed.pdf	Data Security Letter

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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?

> Names are not the only potentially identifying information you have requested. Removing name and replacing it with a study ID is not sufficient to ensure de-identification.
>
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data will be de-identified

Explain what identifiers will be removed and how.
To help ensure and protect the privacy of participants and the confidentiality of research data for the study, we will assign a unique study ID number to each subject's information in place of his/her name and will label data collection forms with the ID number. All electronic files will be stored appropriately using password protection. Only the study team members will have access to study records.

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.

If PID in paper form is used, it will be disposed of through the confidential means of crosscut 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 located in MUSC buildings that are locked and secured with badge access. Faxes in secure locations will be checked daily by research staff to ensure that PID are not left unattended.

MAILING

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

There will be no mailings of PID for this research study.

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.

All electronic files will be stored appropriately using password protection. Access to PID always requires the use of a MUSC username and password, and a two-step verification method in the form of Microsoft Authenticator. Therefore, PID in electronic form will never be left unattended in unsecured locations.

PHYSICAL STORAGE

Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.

Data system security will be ensured by implementing multiple layered firewalls and a network intrusion prevention system for identifying and blocking malicious network activity in real-time. An electronic study log linking patient names with study ID numbers will be kept on a secure server at MUSC.Multiple failed attempts at access to the server causes the user to be locked out from logging into the server.

SERVER SECURITY

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

The data entry management system will be accessed and housed at MUSC. An electronic study log linking patient names with study ID numbers will be kept on a secure server at MUSC, and access to this log will be limited to study personnel.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Please see note above and in the procedures section. Names are not the only identifiers requested for this study. When you state that 'identifiers will be stored separately from analysis data' are you referring only to name or to all identifiers, including address, zip code, etc.?

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All identifiers will be stored separately from analysis data (including name, address, zip code, and phone number). An electronic study log linking patient names with study ID numbers will be kept on a secure server at MUSC, and access to this log will be limited to study personnel.

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 electronic files will be stored appropriately using password protection. Only the study team members will have access to study records. The data entry management system will be accessed and housed at MUSC. Data system security will be ensured by implementing multiple layered firewalls and a network intrusion prevention system for identifying and blocking malicious network activity in real-time.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

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

All MUSC workstations that contain PID have full encryption. MUSC's Epic Electronic Health Record System together with the Institution's electronic authentication system has been found to be a secure and trusted encryption system for research studies. MUSC faculty and staff use electronic applications to maintain records that include human research activities, which are governed by FDA regulations. This statement provides the MUSC response to sponsor requests for certification of compliance with 21 C.F.R. Part 11 ("Part 11") and provides information about MUSC's use of Epic Electronic Health Record System (EHR) with Part 11 requirements.

FIPS 140-2 COMPLIANCE: LAPTOPS

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

All MUSC-issued laptops that contain PID have full encryption. MUSC's Epic Electronic Health Record System together with the Institution's electronic authentication system has been found to be a secure and trusted encryption system for research studies. Study personnel must login to the secure server and then get passed the encrypted authentication system in order to access PID. MUSC faculty and staff use electronic applications to maintain records that include human research activities, which are governed by FDA regulations. This statement provides the MUSC response to sponsor requests for certification of compliance with 21 C.F.R. Part 11 ("Part 11") and provides information about MUSC's use of Epic Electronic Health Record System (EHR) with Part 11 requirements.

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

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

All removable media devices that contain PID have full encryption. MUSC's Epic Electronic Health Record System together with the Institution's electronic authentication system has been found to be a secure and trusted encryption system for research studies. Study personnel must login to the secure server and then get passed the encrypted authentication system in order to access PID.

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.

Data system security will be ensured in all workstations, laptops, and removable media devices by implementing multiple layered firewalls and a network intrusion prevention system for identifying and blocking malicious network activity in real-time.

PASSWORD CONTROLS

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

Access to PID on the secure, encrypted MUSC servers are password protected. MUSC passwords are changed every 180 days to ensure protection of data and information.

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.

All MUSC-issued electronic devices have system security controls for automatic screen timeout after 5 minutes. MUSC systems are equipped with multiple layered firewalls and a network intrusion prevention system for identifying and blocking malicious network activity in real-time.

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.

Data system security will be ensured by implementing multiple layered firewalls and a network intrusion prevention system for identifying and blocking malicious network activity in real-time. This encompasses MUSC-issued emails, website access, and file transfers. All transmissions of PID will use the secure internal network that is password and authentication protected.

INTERNET ACCESSIBILITY

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

PID in an electronic form will NOT be accessible to the internet. It will be stored and saved on a secure MUSC server that is password and authentication protected.

DISPOSING OF PID

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

When disposing of electronic PID, sufficiently secure wiping 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.

Please see note above regarding the need to clarify the informed consent procedures.

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See instructions and examples on CPHS website.

After determination of study eligibility, participants will complete remote e-consent with a study team member. Participants will receive a link to an e-consent form, available via REDCap, that they can review and sign. REDCap is a secure, web-based MUSC Information Technology and Institutional Review Board-approved application to support data capture. Review of the consent form will be paired with a phone call with a research team member to ensure that all questions are answered prior to enrollment. All participants will electronically sign informed consent forms that have been IRB-approved once the study is explained to them in full and they have stated that they understand what is being asked of them. Participants will be given a study phone number and e-mail address to contact for questions. A copy of the signed consent form will also be provided to the subject by their preferred email.

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.

Please see earlier notes regarding questions about the informed consent form.

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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.

TRADEOFFS Stamped ICF_2024.09.30.docx Consent Form

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HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

MPI_Deshmukh-Graboyes_Detailed Budget_V7.xlsx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

A cover letter describes your study briefly in one page (a few paragraphs) and gives a quick understanding of your project. It should be on your institution's letterhead and should be signed by you (as the PI of the project). Please emphasize on the major points regarding the purpose and goal of the study and major steps necessary to complete your project (for example which departments you requested data from, which documents you prepared and attached to the application, etc.)

Would you please attach the document attached in this section in the "Procedures" section of this application and attach a new Cover Letter in this section?

Thanks.

11/07/2024 • Sussan Atifeh • *Not* Internal • Resolved

Cover letter must have the requesting institution's letterhead.

CPHS Cover Letter.docx Cover Letter

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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.

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

California Department of Public Health: California Cancer Registry (CCR)