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 07/14/2025 3:36 PM ET by Ella Starr, MPH, BS

Amendment Header

Amendment Submitter

August 2025 cycle

06/09/2025 • Nicholas Zadrozna • Internal

reviewer notes: Please see email from Ms. Lund to Dr. Graboyes

06/12/2025 • Nicholas Zadrozna • *Not* Internal

Ms. Lund clarified this is a Full Board Amendment and should be discussed in the August 1, 2025 full board meeting. Please see the email attached to this note:

06/12/2025 • Sussan Atifeh • Internal

Re_ Process for CPHS IRB Study Amendments.msg	06/12/2025 11:50 AM ET

Ella Starr, MPH, BS

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

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:

Evan Graboyes, MD, MPH

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

Administrative Contacts:

Name	Role

Protocol Number:

2024-183

Protocol Title:

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

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

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

The protocol was altered to reflect changes in the study procedures. The study procedures were changed to include two new baseline assessments that will be administered to participants, the EQ-5D-5L and MDASI-HN. The study procedures were adjusted to include that participants will be audio and screen-recorded for quality assurance purposes. Changes were made to the informed consent to reflect the addition of two new baseline assessments administered to participants, the EQ-5D-5L and the MDASI-HN. Participants will be audio and screen-recorded for quality assurance purposes, and this is reflected in the informed consent form. The use of videos during patient study visits was added to the protocol. New references were added to the protocol to reflect the sources used to obtain information about the EQ-5D-5L and MDASI-HN assessments. The versions and dates were updated on the protocol and ICF. The teleconference and phone call scripts were altered to reflect new Standard Gamble procedures and to make the scripts easier to understand.

Indicate the Level of Risk involved with the changes proposed.

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

Level of Risk has not changed

PI City Output *(Internal)*

Charleston

PI Location State Output *(Internal)*

South Carolina

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
Ashish Deshmukh, PhD, MPH	Co-Principal Investigator
David Azbill, PhD	Responsible Official
Ella Starr, MPH, BS	Research Team
Evan Graboyes, MD, MPH	Principal Investigator

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

*No change in personnel

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

STUDY PROCEDURES

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

Data Registry
Recruitment-Participant
Surveys

TYPE OF RESEARCH REQUEST

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

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

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

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

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

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.

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

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

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, the MUSC research team makes initial contact with the patient in writing through a patient notification letter in accordance with CCR policies and procedures. We will include the CCR's Cancer Research in California brochure (attached in recruitment materials) as required. At least one week after the letter is sent, we will call patients to recruit them for the study using the approved phone script. Patients will be called up to five times. Patients will then complete remote e-consent with a study team member. Participants will receive a text message or emailed link to an e-consent form, available via REDCap, that they can review and sign. This e-consent from can be texted or emailed to them at the time of the initial recruitment phone call or sent after the initial call and reviewed at a later agreed upon date and time with the potential participant per the preference of the potential participant. Whether at the time of the initial recruitment call or at a later date, 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. Participants will be emailed a copy of the signed consent form.

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 SG. This study does not involve determining treatment options for the participants enrolled. All study procedures will be conducted remotely via video teleconference platform.

The target 'n' for the California portion of the study is 50. To achieve n=50 participants from CCR, we are requesting 250 cases from CCR. We are requesting data from 2019-present.

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) sent from the CCR will be kept in its original electronic format and stored on a password protected, network storage platform to which only IRB approved study team members have access. We will assign a unique study ID number to each subject. The key linking subject ID number to an individual will be stored in the password protected database

We will create a separate REDCap study database with no PII that will link to the CCR data with PII. The REDCap study database will be the database used for the final analysis and will not retain any PII (such as names,

addresses, or specific dates).

In accordance with MUSC policies and procedures and HHS regulations at 45 CFR 46.115(b), we will retain records for 6 year and then electronic data sent from CCR with PII will be destroyed.

June 2025 Amendment:

In the study procedures section, we are requesting to add the following: "This teleconference session will be audio and screen-recorded for quality assurance purposes. The teleconference visit will be guided by an IRB-approved script."

We are requesting to add two more baseline assessments in order to determine patient's current health status and symptom severity post-treatment. These surveys are the EQ-5D-5L and the MDASI-HN. We are requesting to insert the following into the study procedures section of the protocol:
"3. Participants will complete the EQ-5D-5L, a validated measure of health status and health-related quality of life comprised of the following five dimensions: Mobility, Self-care, Usual Activities, Pain/Discomfort and Anxiety/Depression. Each dimension has five response levels of severity: no problems, slight problems, moderate problems, severe problems, unable to/extreme problems."

"4. Participants will complete the MD Anderson Symptom Inventory-Head and Neck (MDASI-HN). The MDASI-HN is a cancer-specific, validated inventory tool used to measure perceived severity, frequency, and impact of HNC-related symptoms. Higher scores indicate worse severity and higher frequency of symptom interference."

We are requesting to add the following to the study procedures section about the standard gamble procedures: "The SG assessment will be guided by videos that participants will watch during the study visit. All study procedures will be conducted remotely via REDCap and video teleconference platform."

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.

JUNE 2025 SOLACE Phone Call Script.2025.05.19	Other Documents
JUNE 2025 SOLACE Teleconference/Standard Gamble Script	Other Documents
OPC Tradeoffs Teleconference Script STAMPED.2024.12.09	Other Documents
HNC Prioritization Scale.docx	Questionnaires
JUNE 2025 EQ-5D-5L	Questionnaires
JUNE 2025 MDASI-HN	Questionnaires
The Standard Gamble Script 2024.09.18	Questionnaires

Deleted Attachments: 6 (Most Recent: MDASI-HN on 07/14/2025 3:05 PM ET)

RECORDING

Will audio or video recording occur?

Yes

Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).
The audio/screen recordings of the study visits will be for quality-assurance purposes only. They will be stored in a password-protected folder where only research staff will have access. After data collection is completed, the audio/screen recordings will be erased and destroyed.

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

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

Not applicable

STATE DEPARTMENT DATA/SPECIMENS

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

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

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). All races, all sexes/genders, and all ethnicities will be recruited. The target 'n' for the California portion of the study is 50. To achieve n=50 participants from CCR, we are requesting 250 cases from CCR. We are requesting data from 2019-present.

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 2019 – present. 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

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.)?

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

Potential participants for recruitment will be identified from cancer registry lists. 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, the MUSC research team makes initial contact with the patient in writing through a patient notification letter in accordance with CCR policies and procedures. We will include the CCR's Cancer Research in California brochure (attached in recruitment materials) as required. At least one week after the letter is sent, we will call patients to recruit them for the study using the approved phone script. Patients will be called up to five times. Patients will then complete remote e-consent with a study team member. Participants will receive a text message or emailed link to an e-consent form, available via REDCap, that they can review and sign. This e-consent from can be texted or emailed to them at the time of the initial recruitment phone call or sent after the initial call and reviewed at a later agreed upon date and time with the potential participant per the preference of the potential participant. Whether at the time of the initial recruitment call or at a later date, 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. Participants will be emailed a copy of the signed consent form.

Attach copies of all recruitment materials.

CCR Brochure	Recruitment Materials
JUNE 2025 SOLACE Phone Call Script.2025.05.19	Recruitment Materials
JUNE 2025 TRADEOFFS ICF Version2.2025.05.19	Recruitment Materials
OPC Tradeoffs Phone Call Script STAMPED.2024.12.06	Recruitment Materials
SOLACE Patient Notification Letter STAMPED	Recruitment

TEMPLATE.2024.12.12.docx	Materials
TRADEOFFS ICF Version 2 Stamped.2024.12.12	Recruitment Materials

Deleted Attachments: 4 (Most Recent: TRADEOFFS ICF Version 2.2025.05.19_STAMPED.docx on 07/14/2025 3:12 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?

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 the study visit 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 upon completion of study activities. Completion of study activities is defined as fully completing the 30-minute teleconference visit with a study staff member. "Partial completion" of the teleconference session (e.g. decline to continue session, patient never shows up to session) will not result in payment.

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.

AUDIO/VIDEO RECORDING RISKS

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

Measures that will be taken to maximize confidentiality and anonymity include the following: (1) all data will be referred to by identification numbers only and (2) data in digital files will be identified by code numbers only. All audio/screen recordings will be stored by their code numbers. Only research staff will have access to the password-protected folder where the audio/screen recordings will be located. There is no increase to potential risk to subject's confidentiality. The likelihood that these methods will effectively protect the confidentiality of participants is considered to be extremely high. No information about participation in the study will be divulged without specific and written consent to release this information. The only exception would be mandated reporting of allegations of child or elder abuse or disclosures of intent to harm self or others. These confidentiality limits will be documented in the written consent form and verbally explained to all participants.

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.

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
Finger, voice print or other bio-metric identifier

TRAINING PROCEDURES

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

All research staff 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.

PII (name, address, telephone number, specific dates) sent from the CCR will be kept in its original electronic format and stored on a password protected, network storage platform to which only IRB approved study team members have access. We will assign a unique study ID number to each subject. The key linking subject ID number to an individual will be stored in the password protected database

We will create a separate REDCap study database with no PII that will link to the CCR data with PII. The REDCap study database will be the database used for the final analysis and will not retain any PII (such as names, addresses, or specific dates). No PII will be published in the final analysis.

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?

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.

We will not report cells with values less than 10. We are not reporting state-specific data.

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

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.
PII (name, address, telephone number, specific dates) sent from the CCR will be kept in its original electronic format and stored on a password protected, network storage platform to which only IRB approved study team members have access. We will assign a unique study ID number to each subject. The key linking subject ID number to an individual will be stored in the password protected database

We will create a separate REDCap study database with no PII that will link to the CCR data with PII. The REDCap study database will be the database used for the final analysis and will not retain any PII (such as names, addresses, or specific dates).

In accordance with MUSC policies and procedures and HHS regulations at 45 CFR 46.115(b), we will retain records for 6 year and then electronic data sent from CCR with PII will be destroyed.

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.

All PID will be stored in an electronic format. No PID will be recorded on paper forms.

FAXING

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

We will not fax any PID.

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.

We will initially contact patient by mail as required by the CCR. After that initial mailing, there will be no further mailing of PID by our study team.

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.

We will not store any data on laptop computers or portable electronic storage media.

PHYSICAL STORAGE

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

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.

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 IRB-approved study personnel.

DISK STORAGE

State whether all disks with PID will be destroyed.

We will not store any PID on disks.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All 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.

See instructions and examples on CPHS website.

Once the list of eligible patients is obtained along with their contact information, the MUSC research team makes initial contact with the patient in writing through a patient notification letter in accordance with CCR policies and procedures. We will include the CCR's Cancer Research in California brochure (attached in recruitment materials) as required. At least one week after the letter is sent, we will call patients to recruit them for the study using the approved phone script. Patients will be called up to five times. Patients will then complete remote e-consent with a study team member. Participants will receive a text message or emailed link to an e-consent form, available via REDCap, that they can review and sign. This e-consent from can be texted or emailed to them at the time of the initial recruitment phone call or sent after the initial call and reviewed at a later agreed upon date and time with the potential participant per the preference of the potential participant. Whether at the time of the initial recruitment call or at a later date, 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.

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.

JUNE 2025 TRADEOFFS ICF Version2.2025.05.19	Consent Form
TRADEOFFS ICF Version 2 Stamped.2024.12.12	Consent Form

Deleted Attachments: 2 (Most Recent: TRADEOFFS ICF Version 2.2025.05.19_STAMPED.docx on 07/14/2025 3:35 PM ET)

HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Amendment Changes

List the pages and questions that have been changed.

Page 4: 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

Page 4: RECORDING
Will audio or video recording occur?

Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).

Page 5: 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.)?

Page 6: AUDIO/VIDEO RECORDING RISKS
State if audio/video taking could increase potential risk to subject's confidentiality.

Page 7:HIPAA IDENTIFIERS (Required)
Please identify which HIPAA Identifiers you plan to request as part of your submission.

Page 11: 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.

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

CPHS Budget.xlsx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

CPHS Cover Letter.docx 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.

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

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

PI Signature for Coordination Submission (Amend) - Submitted 07/15/2025 8:37 PM ET by Evan Graboyes, MD, MPH

PI Review

Please click "Next" and "Submit" in order to submit this application, regardless of whether or not it is ready for review. If you indicated it is ready for review, the amendment will be submitted to the CPHS Office, and if not, it will be returned to the individual who completed the form for changes.

Is this application ready to be reviewed by the IRB? If not, choose no to have the application sent back to the coordinator for revisions.

Yes

To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this application is accurate and reflects the proposed research and that you attest to the conflict of interest disclosures for all study team members.

Signed Tuesday, July 15, 2025 8:37:40 PM ET by Evan Graboyes, MD, MPH

Notify IRB for Pre-Screening
- Submitted 07/16/2025 11:05 AM ET by Sussan Atifeh

Internal IRB Screening

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

Is this study ready to be reviewed by the CPHS panel?

Yes

Choose the IRB committee to review this study (this defaults to CPHS)

CPHS

Level of Review Determination (once the level of review is assigned for this project, do not change this answer unless the reviewer/committee has decided that the study requires a different level of review)

Full Board Minimal Risk

Please provide a rationale for your level of review preliminary determination
The protocol was altered to reflect changes in the study procedures. The study procedures were changed to include two new baseline assessments that will be administered to participants, the EQ-5D-5L and MDASI-HN. The study procedures were adjusted to include that participants will be audio and screen-recorded for quality assurance purposes. Changes were made to the informed consent to reflect the addition of two new baseline assessments administered to participants, the EQ-5D-5L and the MDASI-HN. Participants will be audio and screen-recorded for quality assurance purposes, and this is reflected in the informed consent form. The use of videos during patient study visits was added to the protocol. New references were added to the protocol to reflect the sources used to obtain information about the EQ-5D-5L and MDASI-HN assessments. The versions and dates were updated on the protocol and ICF. The teleconference and phone call scripts were altered to reflect new Standard Gamble procedures and to make the scripts easier to understand.

Choose the CPHS Chair
Catherine Hess, PhD

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

Assign to Cycle

August

Assign to cycle year
2025

Load into IRBManager (Amendment)
- Submitted 07/16/2025 11:05 AM ET by The System

Chair Review and Full Board Set-Up
- Submitted 07/16/2025 11:06 AM ET by Sussan Atifeh

Full Board Set Up

Project number

2024-183

The office will complete the questions on this page and submit the form after the teleconference with the chairs regarding this project is completed.

Confirmation of level of review

Full Board Minimal Risk

Provide the rationale for the level of review determination
Ms. Lund clarified this is a Full Board Amendment and should be discussed in the August 1, 2025 full board meeting.

Assign SME to study

Laura Lund, MA

Enter the meeting date for this project

08/01/2025

SME Review

SME review

After reviewing the application, complete the question(s) below. If you wish to make comments on the application for the researcher, use the 'add note' feature on each question (be certain to unmark the internal only box and do not mark changes required). To navigate the application, you can either use the 'previous' button at the bottom of the page or from the drop down at the top of this page choose 'view previous stages'. Once you have completed the questions that appear on this page (different questions will appear depending on your answer to the first question), you will need to click 'next' (from either the top of the bottom of the screen) and then click 'submit'.

If you are requiring revisions before the full committee review, the form will be returned to the researcher for revisions and returned to you upon re-submission.

Does the researcher need to provide additional information/revisions before the committee meeting? If there is insufficient time for the researcher to make changes prior to the committee meeting, choose 'no' in order to route the form correctly.

No answer provided.

In order to either return this application to the researcher or to move forward for the full meeting review, click 'next' and 'submit' on the next screen.