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

Amendment Header

Amendment Submitter

February 2025 cycle
12/23/2024 • Nicholas Zadrozna • Internal

Emily Dang, MPH
Email: emilydan@usc.edu **Business:** (323) 865-3000

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:

Jennifer Tsui, PhD, MPH
Email: tsuijenn@usc.edu **Business:** (310) 597-0962

Administrative Contacts:

Name	Role

Protocol Number:

2023-117

Protocol Title:

Assessing Cervical Cancer Healthcare Inequities in Diverse Populations: The ACHIEVE Study

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

Recruitment strategy and/or materials
Addition and/or removal of project personnel
Data collection

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

Please add the CCR brochure to the 12 month follow up mailing packet.

01/07/2025 • Laura Lund, MA • *Not* Internal

We are proposing the following changes to our current protocol, which was mostly recently approved by CPHS under expedited review on November 21, 2024:

1) 12 MONTH FOLLOW-UP SURVEY AND RECRUITMENT MATERIALS: We are requesting the approval of the English version of the 12 Month Follow-up Survey and Recruitment Materials. Members of our participant cohort will be requested to participate in Step 3 of the study, the 12 Month Follow-up Survey. LACSP will oversee all components of the 12 Month Follow-up Survey recruitment process for cases diagnosed with cervical cancer in Los Angeles and who completed the baseline survey (step 1). Approximately 12 months after a participant completes their survey, LACSP staff will mail a 12 Month Follow-up Survey study packet with an invitation letter, the survey, consent form, and instructions for how to complete the survey. Participation in Step 2, Medical Records Authorization, is not a requirement for invitation to the 12 Month Follow-up Survey component of the study. Participants will receive a $50 incentive upon completion of the survey. During the course of the 12 Month Follow-up Survey recruitment process, participants will receive a maximum of 8 phone calls and two mailings: the initial 12 Month Follow-up Survey study packet and a reminder letter. Once approvals for these materials are received, we will request for Spanish and Traditional Chinese translation and submit at a later amendment for approval.

We are also requesting a change in Responsible Official from Dr. Howard Hu to Dr. Ricky Bluthenthal.

Indicate the Level of Risk involved with the changes proposed.

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

Level of Risk has not changed

PI City Output *(Internal)*

Los Angeles

PI Location State Output *(Internal)*

California

Personnel Information for Amendment

Please complete the questions below.

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

New Contact Form

Existing Personnel

Name	Role
Adana Llanos, PHD, MPH	Co-Principal Investigator
Chanita Hughes Halbert, PhD	Co-Principal Investigator
Denise Modjeski, MS	Research Team
Emily Dang, MPH	Research Team
Howard Hu, ScD	Responsible Official
Jennifer Tsui, PhD, MPH	Principal Investigator
Juanjuan Zhang, MS	Research Team
Katherine Wojcik, PhD	Research Team
Lihua Liu, PhD	Co-Principal Investigator
Sz-Ying Lee, BSN	Research Team
Yesenia Carranza	Research Team

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

Change in Responsible Official

Please enter the email address of the new Responsible Official.

Include previous Responsible Official under personnel to remove below.

Ricky Bluthenthal, PhD

Email: rbluthen@usc.edu **Business:** (323) 442-8236

REMOVE CONTACT(S)

Click 'Add Contact' button to enter in the email address of any staff (including co-PI or RO) from the above list that are being removed from the study.

Howard Hu, MD, MPH, ScD

Email: howardhu@usc.edu **Business:** (323) 865-0803

Project Information

SUBMITTER

Application completed by:

Emily Dang, MPH
Email: emilydan@usc.edu **Business:** (323) 865-3000

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).

Assessing Cervical Cancer Healthcare Inequities in Diverse Populations: The ACHIEVE Study

STUDY PROCEDURES

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

Data Registry
Recruitment-Participant
Surveillance Data
Surveys

TYPE OF RESEARCH REQUEST

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

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

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

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

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

Common rule/Human subjects

PROJECT TYPE DETAILS

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

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

Minimal Risk
Non-English translation required
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.

Economically or Educationally Disadvantaged Persons

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Federally funded

Enter name of federally-funded source.
National Institutes of Health

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

02/26/2024

ANTICIPATED PROJECT END DATE

11/30/2027

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.

The goal of this study, funded through a 5 year grant from the National Institute of Minority Health and Health Disparities (Grant # 1R01MD018250-01), is to leverage two population-based Surveillance, Epidemiology, and End Results (SEER) Program registries (New Jersey State Cancer Registry and Los Angeles Cancer Surveillance Program), to prospectively examine the impact of micro-, mezzo-, and macro-level factors – with an emphasis on macro-level factors – on receipt of guideline concordant treatment for and survival from cervical cancer. We will use existing data from the Los Angeles Cancer Surveillance Program to identify, recruit, and survey patients for our study. Our first aim is to examine the impact of structural racism and health system-related factors on inequities in treatment delivery and survivorship care, translating to poorer outcomes among racial and ethnic minority, immigrant, and low socioeconomic status individuals with cervical cancer. Our second aim is to evaluate the association of social and structural factors on cervical cancer outcomes. Procedures for the first and second aim are provided in this project application.

Our third aim is to identify actionable strategies for addressing social and structural risks and health system level factors to optimize delivery of equitable cervical cancer care through participatory engagement of stakeholders. For the third aim, we plan to invite key stakeholders to participate in qualitative interviews. Interviews will begin during Year 3 of the study and an amendment will be submitted detailing the recruitment process, data collection, and interview guides at a later time.

Successful accomplishment of the proposed aims will result in high impact findings on the multilevel causes of suboptimal cervical cancer treatment and poorer survival outcomes among marginalized groups to develop actionable system-level interventions to address the persistent cervical cancer inequities. The study design also allows for the expansion to additional registries, geographies, and target communities for recruitment in our future work. Study end products will also include dissemination of study findings to community and health care partners, broader stakeholders of this study, and the scientific audience through presentations, conference abstracts and peer-reviewed journal articles.

MAJOR RESEARCH QUESTION

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

What is the impact of structural racism and health system-related factors on inequities in treatment delivery and survivorship care, translating to poorer outcomes among racial and ethnic minority, immigrant, and low socioeconomic status individuals with cervical cancer?

STUDY PROCEDURES

Describe in detail all procedures for this research. Do not attach grant applications or similar documents. Information in this application must be sufficient to fully explain the procedures without such documents

The language below is in the 12 month follow up consent form. However, you are not asking individuals for a HIPAA authorization as part of the follow up survey--permission to use medical records and PHI cannot be obtained through the consent form, there must be a HIPAA authorization. To make it less confusing for the participant, it would be better to change the language here to remind them that they may or may not previously have signed a HIPAA authorization in the earlier arm of this study and that, if they did provide a HIPAA authorization, the information they provide here will be linked with their medical record data.

Excerpt from consent form: Access to your health information is one part of this study. If you choose to consent, you are authorizing us (i.e., your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive.

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care that is needed for this research purpose, including the physicians treating your cervical cancer.

01/07/2025 • Laura Lund, MA • *Not* Internal

The phrase below is in the introduction to the survey. Participants should clearly understand that they can skip any question at any time, not just because they are not comfortable. Consider rewording to something like --...skip any question you don't want to answer.

Survey intro states: While some of the questions may be considered sensitive, please know that you have the option to skip any question you don’t feel comfortable answering.

01/07/2025 • Laura Lund, MA • *Not* Internal

You state: We have attached a table in our protocol that includes how the follow-up survey content compares to the baseline survey.

I was not able to find this document?

01/07/2025 • Laura Lund, MA • *Not* Internal

In your description of recruitment and consent process you are giving individuals who choose the phone administration modality the opportunity to consent either on paper or online prior to starting the interview, is that correct? You have provided for those who participate by phone to complete the consent on line, confirmed by the staff person who then starts the interview after the consent is complete. For those who choose to consent on paper but complete the survey by phone, are you waiting to receive the signed consent prior to starting the phone interview?

01/07/2025 • Laura Lund, MA • *Not* Internal

The consent form should tell participants that you will be linking the answers they provide with the baseline survey information they shared previously and their cancer registry information.

01/07/2025 • Laura Lund, MA • *Not* Internal

For this project, we will be working with the Los Angeles County Cancer Surveillance Program (LACSP), the population-based cancer registry for Los Angeles County. The LACSP operates within the administrative structure of the University of Southern California (USC) School of Medicine. Thus, all LACSP staff are employed by USC. Dr. Lihua Liu, one of the Co-Investigators, is the Director of LACSP and an Associate Professor at USC Keck School of Medicine. This project is part of a NIH funded multi-site study led by two multi-Principal Investigators (Jennifer Tsui, USC & Adana Llanos, Columbia University). Given that this is a MPI study, Columbia University Institutional Review Board will serve as the central IRB. We have received approval from USC IRB for a Ceded IRB to Columbia University as the reviewing IRB.

Overview of data collection:

For Aims 1 and 2, staff from the LACSP will identify a cohort of patients diagnosed in 2020-2025 with histologically confirmed invasive cervical cancer patients to be part of the ACHIEVE Study cohort. Based on historical data, we estimate there will be 3,048 eligible cases identified over the 4 years. We intend to contact all 3,048 eligible cases through mailed

recruitment. However, we estimate enrolling a minimum of 672 participants (431 through New Jersey State Cancer Registry and 241 Los Angeles Cancer Surveillance Program) based on consultation with our registry partners and other similar case recruitment studies into the cohort between the second half of Year 1 and the first half of Year 4. We estimate there will be 3,048 cervical cancer cases in the LACSP database between 2020-2025. We anticipate 85% of cases in the LACSP database will be found to be ineligible after patient contact. In addition, we anticipate 25% of remaining eligible cases will consent to participate and 93% of those that have consented will participate in study activities. Thus, we estimate a total of 672 cases will be enrolled during the study period.

We will obtain retrospective data (collected at baseline) and prospective data (collected 12 months after baseline) for each cohort member from the following sources: 1) cancer registry records; 2) self-reported surveys; 3) medical records; and 4) publicly available datasets. After receiving data from these sources, we plan to link participants' medical record information with their survey answers and information we receive from LACSP.

This project is covered by a Certificate of Confidentiality from the National Institutes of Health. We cannot release or use information, documents, or samples that may identify participants in any action or suit unless participants consent. We also cannot provide them as evidence unless participants have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Baseline Survey:

Staff from LACSP will initiate patient contact by sending eligible cases the Baseline Survey Recruitment packet requesting participation in the study, which includes an introductory letter, written informed consent form for the baseline survey, baseline survey, CCR brochure, and a postage paid return envelope, as well as instructions for completing the survey via other modes (i.e., online via REDCap link or by phone with the MPIs' research study staff). Only English, Spanish and Mandarin speaking or English, Spanish, and Chinese reading participants will be recruited from LACSP. Persons who don't speak English, Spanish, or Mandarin or can not read English, Spanish, or Chinese are ineligible for this study among LACSP participants. We will use the registry variables NHIA and NAPIIA to identify persons with Spanish or Chinese identification, respectively, who will then receive study packets in both English and the specific ethnic languages. We will also include a "preferred language sheet" in dual-language packets asking them to complete the materials only in their preferred language. Certified translations in Spanish and Chinese for all Baseline Survey study materials are attached.

Participants are requested to read and complete the the written consent form for the baseline survey prior to completing the baseline survey. Instructions for completing the consent form are listed as the first step on the instructions for completing the survey. Those that opt for the paper survey are requested to read and sign the consent form prior to starting the survey. Those that choose to complete the survey online will be able to

access the informed consent form on REDCap prior to beginning the survey. Those that would like to complete the survey over the phone are instructed to contact a study team member for additional instructions for providing consent. Our baseline survey recruitment telephone script provides a standard script for our staff to ask participants for their preference for providing written consent. Participants will be provided the option to receive the link to the consent phone via text message or email.

Some of the survey questions are sensitive, however no studies have systematically examined how intersectionality of multilevel factors – including indicators of structural inequities and racism (e.g. related to nativity, immigration, language, and other structural/social factors that are understudied) – impact cervical cancer outcomes, a disease that is preventable but persistently overburdens marginalized communities. Thus, a rigorous, comprehensive analysis of individual-, area, and health system-level factors that predict suboptimal treatment receipt and cervical cancer survival, such as this project, will yield critical knowledge to inform actionable health care delivery practice change and policies to close persistent disparities in care quality and survival. We have made minor changes to the previously approved baseline survey to improve the response categories and wording of some survey items. No new content or survey topics have been added to the baseline survey.

Historically, race has been used as a predictor of poorer outcomes at the individual-level or as a confounder (at the population-level) in public health research, rather than as a proxy for a myriad of health risks resulting from existence in sociopolitical systems of power and oppression based on race. Limiting our understanding of racism to interpersonal and psychosocial dimensions fosters the notion that race and racism are personal constructs, and obscures and absolves racism's systemic roots. To promote health equity, population health research must clearly operationalize structural racism, accounting for its multi-dimensional nature, whereby internalized, interpersonal, and institutional levels interact to influence a range of health outcomes. The problem with existing structural racism metrics is that they focus on single dimensions of structural racism, which don't convey how many institutions and industries contribute to the observed health disparities. Multiple dimensions of structural racism (operationalized in this study as social and neighborhood-level deprivation largely due to long-term impacts of civil rights laws, legal racial discrimination, economic deprivation, police violence/over-policing, and/or residential segregation and housing discrimination) may follow a common path (e.g., education inequity leads to employment inequity) or may interact thereby having cumulative effects on health (e.g., education inequity among inhabitants of segregated areas). To adequately address structural factors, and move beyond standard individual demographic factors, our study requires measurement of intersectional and multilevel influences, immigration, police encounters, and neighborhood concerns. We base these measures off other peer-reviewed studies, police encounter scales from other population-based research, and neighborhood concerns from scales in the PhenX Toolkit. Our established research team, including partners at the cancer registries and co-investigator Hughes-Halbert senior investigator and Director of Cancer Equity at USC Norris, will work together to ensure confidentiality and data protection.

Medical Records:

After the completion and return of the baseline survey, which will take about 30-60 minutes to complete, LACSP staff will send the baseline survey incentive to participants ($50) and invitation for participants to move on to the Medical Records phase of the study. The Medical Records recruitment packet will include: a Medical Records introductory letter and the Medical Records Informed Consent Booklet. This booklet consists of 3 forms and an instruction sheet. The three forms are an Informed Consent Form for medical records, a HIPAA authorization for patients to sign indicating their willingness to have their medical records released to the for abstraction, and a Healthcare Source Form. Certified translations in Spanish and Chinese for all Medical Records study materials are attached. We also will provide a postage paid return envelope for the return of this booklet. Participants will be informed that they can decide to participate or not participate in the sharing of medical records upon receipt of the medical records introductory letter. Participants will also be informed that they will still be eligible to complete the 12 month follow-up survey if they decline to participate in the sharing of medical records. Following the receipt of these forms, our LACSP staff will then contact the appropriate facilities and providers to coordinate retrieval of the relevant records. Upon receipt of completed written consent for Medical Records, HIPAA authorization, and healthcare source form registry staff will send thank you letters and incentive payments to participants ($25) and contact hospitals and providers/clinics to request records.

Upon receipt or written Informed Consent for Medical Records, HIPAA Authorization for medical records and Healthcare Source Form, we plan to obtain and abstract comprehensive diagnostic and treatment information (dates and location of treatments received, providers seen [e.g., outpatient visits – primary care, specialists] and inpatient visits – emergency department, hospitalizations], care received for and management of comorbidities, medications prescribed) from participants' medical records.

For the collection of additional relevant macro-level data, specific to hospital and system-level factors, we will use publicly available hospital/health system data sources, such as American Hospital Association data. Additional health system factors including hospital Commission on Cancer (CoC) accreditation of the primary treatment facility, of the follow-up care/treatment facility (if any), of the survivorship care facility (if any), and whether facility is a designated or affiliated with a National Cancer Institute (NCI)-designated cancer center. CoC accreditation status for each facility reported by the participant will be abstracted from the American College of Surgeons database and we will confirm NCI-designation or affiliation through web searches. We will also use residential and health care provider zip codes or geocode information will be used to link to CMS Office of Minority Health Mapping Medicare Disparities (MMD) Tool and the Centers for Medicare & Medicaid Services (CMS) CAHPS and HEDIS Data where feasible.

12 Month Follow-up Survey:

Registry staff will send participants the 12 Month Follow-up Survey Recruitment packet requesting participation in the 12 Month Follow-up Survey (Step 3) portion of the study study approximately 12 months after completion of the baseline survey. Participants are eligible to participate in Step 3 if they provided consent for the Baseline Survey and completed the Baseline Survey. Participation in the Medical Records portion of the study is not a requirement to participate in the 12 Month Follow-up Survey portion of the study. This packet includes an introductory letter, written informed consent form for the 12 Month Follow-up Survey ,12 Month Follow-up Survey, and a postage paid return envelope, as well as instructions for completing the survey via other modes (i.e., online via REDCap link or by phone with the MPIs' research study staff). Participants will be informed that they can decide to participate or not participate upon receipt of the 12 month letter. Upon receiving completed 12 Month Follow-up Survey, registry staff will mail the $50 incentive to participants. We have attached a table in our protocol that includes how the follow-up survey content compares to the baseline survey. In brief, the follow-up survey will continue to ask questions micro-, mezzo-, and macro-level factors, but will focus more on survivorship care periods instead of screening, diagnosis, and acute treatment experiences of care.

Participants are requested to read and complete the the written consent form for the 12 Month Follow-up Survey prior to completing the 12 Month Follow-up Survey. Instructions for completing the consent form are listed as the first step on the instructions for completing the survey. Those that opt for the paper survey are requested to read and sign the consent form prior to starting the survey. Those that choose to complete the survey online will be able to access the informed consent form on REDCap prior to beginning the survey. Those that would like to complete the survey over the phone are instructed to contact a study team member for additional instructions for providing consent. Our 12 Month Follow-up Survey recruitment telephone script provides a standard script for our staff to ask participants for their preference for providing written consent. Participants will be provided the option to receive the link to the consent phone via text message or email. We will use the participant's preferred language identified from Baseline Survey recruitment to identify whether they will receive the 12 Month Follow-up Survey packets in both English and the specific ethnic languages. We will also include a "preferred language sheet" in dual-language packets asking them to complete the materials only in their preferred language. Certified translations in Spanish and Chinese for the 12 Month Follow-up Survey, recruitment materials, and informed consent form will be provided in a subsequent amendment after the English version of the material is approved.

Analysis for Aims 1 and 2:

For evaluating the association of micro-, mezzo-, and macro-level social and structural factors on screening history, diagnostic barriers and receipt of guideline-concordant treatment for invasive cervical cancer: We will first examine the distribution of each social and structural factor using histograms, boxplots, and means and standard deviations for continuous variables, and bar graphs and frequencies for categorical and ordinal

variables. The association of each micro-level social and structural factor on the primary outcome (receipt of guideline-concordant treatment) will be assessed using logistic regression model. The association of each mezzo- or macro-level factor will be assessed using mixed effects logistic regression model with community or healthcare system as random intercepts to consider the potential for clustering effects. Models will include confounders – identified using directed acyclic graphs (DAGs), and factors strongly predictive of the outcome but unaffected by exposure – to improve model fit. Significant confounders will be included in mixed effects multivariable logistic regression models to evaluate the common impact of micro-, mezzo-, and macro-level factors on the primary and secondary outcomes. We will assess the impact of primary predictors of interest (i.e. on the outcomes one at a time), adjusting for potential confounders. To deal with the multiple testing issues, the Benjamin-Hochberg procedure will be used to control the false discovery rate. To study the common effects of independent variables on clinical outcomes, we will include all independent variables in the regression model, adjusting for potential confounders. We will select strategies for handling missing data based on the type of data missing and extent of missingness. If significant proportions (>15%) of data are missing for any given variable, multiple imputation will be used. Min to add multicollinearity here: We will use elastic net models (i.e., combination of LASSO and Ridge regression) to handle potential collinearity among independent variables and confounders, as well as to identify important independent variables.

For evaluation of the association of micro-, mezzo-, and macro-level social and structural factors on cervical cancer outcomes: We will assess the impact of each micro-level factor on overall survival and cervical cancer-specific survival using Cox model. For each of the mezzo- and macro-level factors, Cox frailty models will be used to consider the community or healthcare system random effects. Multivariable Cox or Cox frailty models will be used to adjust for confounders and evaluate the common effects of all social and structural risk factors. For patient-reported outcome scores, linear regression and mixed effects linear models will be used to assess the effects of the risk factors on each outcome. We will explore stratified analyses by stage (locally advanced vs. early-stage) to examine between-group differences in the associations of interest.

November 2024 amendment:
We have included the Medical Records Physician Letter as part of the November 2024 amendment. The research and registry staff will send the Medical Records Physician Letter along with the patient's HIPAA Authorization to their providers and health care facilities for the purpose of medical records abstraction. We will only request a patient's medical records after the patient has signed both the HIPAA Authorization and consent form.

Additionally, LACSP staff will send a baseline survey reminder letter with details on how to access the survey online to participants who do not respond after 4 weeks of initial contact. The inclusion of the mailing of a reminder letter for the baseline survey recruitment process was recommended by LACSP staff given its effectiveness in other LACSP recruitment studies. This also ensures consistency across the cancer

registries engaged in this study as the New Jersey State Cancer Registry also mails a second set of materials after 4 weeks of initial contact.

December 11th amendment:
We have revised the Baseline Survey after consulting with our research team and CAB. The changes are minimal and primarily focused on updating skip patterns, including a "Decline to answer" response category, and revising questions to more accurately capture participant's sociodemographic characteristics.

We have attached the Spanish and Traditional Chinese translated Baseline Survey Reminder Letter. The English version of this letter was previously submitted and approved by CPHS.

December 20th amendment:
We have included the 12 Month Follow-up Survey for the December 20th amendment. We detailed the 12 Month Follow-up Survey recruitment process above. The process mirrors the Baseline Survey recruitment process, including the utilization of a 12 Month Follow-up Survey reminder letter after 4 weeks of initial contact from.

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.

ACHIEVE LA 12M Survey Consent Form English v. 06.14.24.docx	Consent Form
ACHIEVE LA Baseline Survey Consent Form Chinese v. 06.14.24.docx	Consent Form
ACHIEVE LA Baseline Survey Consent Form English v. 06.14.24 CLEAN.docx	Consent Form
ACHIEVE LA Baseline Survey Consent Form Spanish v. 06.14.24.docx	Consent Form
ACHIEVE LA Medical Records Consent Form Chinese v. 06.14.24.docx	Consent Form
ACHIEVE LA Medical Records Consent Form English v. 06.14.24 CLEAN.docx	Consent Form
ACHIEVE LA Medical Records Consent Form Spanish v. 06.14.24.docx	Consent Form
ACHIEVE USC IRB Relying on Columbia IRB.pdf	External IRB Approvals
ACHIEVE LA Medical Records HIPAA Authorization Chinese v. 06.14.24.docx	HIPAA Documents
ACHIEVE LA Medical Records HIPAA Authorization English v.4 CLEAN.docx	HIPAA Documents
ACHIEVE LA Medical Records HIPAA Authorization Spanish v. 06.14.24.docx	HIPAA Documents
ACHIEVE 12M Survey English v. 12.20.24.docx	Instruments
ACHIEVE Baseline Survey Chinese v. 07.30.24 CLEAN.docx	Instruments

ACHIEVE Baseline Survey English v. 07.30.24 CLEAN.docx	Instruments
ACHIEVE Baseline Survey Spanish v. 07.30.24 CLEAN.docx	Instruments
ACHIEVE LA Medical Records Healthcare Source Form Chinese v. 06.14.24.docx	Instruments
ACHIEVE LA Medical Records Healthcare Source Form English v.2 CLEAN.docx	Instruments
ACHIEVE LA Medical Records Healthcare Source Form English v.2 TRACKED.docx	Instruments
ACHIEVE LA Medical Records Healthcare Source Form Spanish v. 06.14.24.docx	Instruments
ACHIEVE - Table on independent variables collected at baseline and follow-up.docx	List of Variables
ACHIEVE LA 12M Survey Instructions English v. 06.14.24.docx	Misc/Other
ACHIEVE LA Baseline Survey Instructions Chinese v. 07.30.24 CLEAN.docx	Misc/Other
ACHIEVE LA Baseline Survey Instructions Chinese v. 07.30.24 TRACKED.docx	Misc/Other
ACHIEVE LA Baseline Survey Instructions English v. 07.30.24 CLEAN.docx	Misc/Other
ACHIEVE LA Baseline Survey Instructions English v. 07.30.24 TRACKED.docx	Misc/Other
ACHIEVE LA Baseline Survey Instructions Spanish v. 08.05.24 CLEAN.docx	Misc/Other
ACHIEVE LA Baseline Survey Instructions Spanish v. 08.05.24 TRACKED.docx	Misc/Other
ACHIEVE LA Medical Records Instructions Chinese v. 06.14.24.docx	Misc/Other
ACHIEVE LA Medical Records Instructions English v.1.docx	Misc/Other
ACHIEVE LA Medical Records Instructions Spanish v. 06.14.24.docx	Misc/Other
ACHIEVE LA Preferred Language Sheet Chinese v. 06.14.24.docx	Misc/Other
ACHIEVE LA Preferred Language Sheet Spanish v. 06.14.24.docx	Misc/Other
CCR Brochure.pdf	Misc/Other
Achieve Study Response to CPHS Deferred Approval Letter_Nov 1 _2023FINAL.pdf	Other Documents
ACHIEVE LA Baseline Survey Participant Recruitment Letter Chinese v. 08.01.24 CLEAN.docx	Recruitment (non-English)
ACHIEVE LA Baseline Survey Participant Recruitment Letter Spanish v. 08.05.24 CLEAN.docx	Recruitment (non-English)
ACHIEVE LA Baseline Survey Thank You Medical Records Letter Chinese v. 08.01.24 CLEAN.docx	Recruitment (non-English)

ACHIEVE LA Baseline Survey Thank You Medical Records Letter Spanish v. 08.05.24 CLEAN.docx	Recruitment (non-English)
ACHIEVE LA Medical Records Thank You Letter Chinese v. 08.01.24 CLEAN.docx	Recruitment (non-English)
ACHIEVE LA Medical Records Thank You Letter Chinese v. 08.01.24 TRACKED.docx	Recruitment (non-English)
ACHIEVE LA Medical Records Thank You Letter Spanish v. 08.06.24 CLEAN.docx	Recruitment (non-English)
ACHIEVE LA 12M Survey Participant Recruitment Letter English v. 06.14.24.docx	Recruitment Materials
ACHIEVE LA 12M Survey Participant Reminder Letter English v. 06.14.24.docx	Recruitment Materials
ACHIEVE LA 12M Survey Thank You Letter English v. 06.14.24.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Participant Recruitment Letter English v. 08.01.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Participant Reminder Letter English v. 11.05.24.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Thank You Medical Records Letter English v. 08.01.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Medical Records Physician Letter v. 11.1.24.pdf	Recruitment Materials
ACHIEVE LA Medical Records Thank You Letter English v. 08.01.24 CLEAN.docx	Recruitment Materials

Deleted Attachments: 7 (Most Recent: ACHIEVE 12M Survey English v. 12.20.24.docx on 12/20/2024 12:45 PM ET)

RECORDING

Will audio or video recording occur?

No

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

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

Not applicable

STATE DEPARTMENT DATA/SPECIMENS

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

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	Los Angeles Cancer Surveillance Program - California Cancer Registry

Study Population

POPULATION DESCRIPTION

Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects such as: age; sex; ethnicity; and number of participants. Include requested participant number.

Los Angeles County Cancer Surveillance Program (LACSP) staff will identify all eligible cases in the LACSP database. We estimate enrolling 672 participants (431 through NJSCR and 241 through LACSP) into the cohort between the second half of Year 1 and the first half of Year 4. The LACSP staff will assemble a cohort of approximately 241 non-Hispanic White (NHW), non-Hispanic Black (NHB), Hispanic/Latina, and Asian Pacific Islander (API) cervical cancer cases diagnosed between 2020-2025. Eligibility criteria include: 1) Individuals with a cervix diagnosed with cervical cancer between 2020-2025; 2) resident of California at cervical cancer diagnosis; 3) able to speak and read English, Spanish, or Mandarin (Chinese); 4) aged 21-79 years.

We have described our process in ensuring that the introductory letter is in the correct language for recipients in the study procedures and have copied our response in this form as well. Only English, Spanish and Mandarin speaking participants will be recruited from LACSP. Persons who cannot complete the survey in English, Spanish, or Chinese or who don’t speak English, Spanish, or Mandarin are ineligible for this study among LACSP participants. We will use the registry variables NHIA and NAPIIA to identify persons with Spanish or Chinese identification, respectively, who will then receive study packets in both English and the specific ethnic languages. We will also include a “preferred language sheet” in dual-language packets asking them to complete the materials only in their preferred language. An example of this sheet in Spanish and Chinese that was used in a similar study is now included with this application. Certified translations in Spanish and Chinese for all study materials will be provided in a subsequent amendment after the English version of the study materials is approved.

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.

Los Angeles County Cancer Surveillance Program (LACSP) staff will identify all eligible cases in the LACSP database diagnosed from 01/01/2020 through 12/31/2025. Based on discussions with the LACSP staff, we estimate there will be 1256 eligible cases identified from the LACSP database.

The requested list of variables has been attached. The USC team has worked with the Columbia University team and NJSCR staff to ensure requested variables are concordant across sites.

After feedback from CCR on our original requested variable list, we have made edits to the requested variable list to replace nonapplicable variables and include suggested variables.

Upon receipt of HIPAA authorizations for medical records and records retrieval, comprehensive diagnostic, and treatment information (dates and location of treatments received, providers seen [e.g., outpatient visits – primary care, specialists] and inpatient visits – emergency department, hospitalizations], care received for and management of comorbidities, medications prescribed) will be abstracted from medical records. For the collection of additional relevant macro-level data, specific to hospital and system-level factors, we will use publicly available hospital/health system data sources. This will be supplemented with data from medical records and self-reported questionnaire data.

We will collect provider information in the baseline survey and also use relevant place of service codes from LACSP to identify providers and obtain provider characteristics where feasible (specialty, location etc). We have added a description of the medical records abstraction fields in our protocol. Briefly, we will use medical records in addition to cancer registry information and patient surveys, to obtain provider and health system characteristics. At the healthcare system-level, we are interested in the impact of the following factors:

• Characteristics of providers involved in cervical cancer diagnosis and treatment: specialty (gynecologic oncologist, gynecology/obstetrics, other specialty), practice type (community hospital affiliated, academic medical

center, private practice), racial/ethnic concordance with patient (yes vs. no). We will use medical records as the primary data source to obtain provider characteristics where possible, and then use patient report through surveys or cancer registry data if medical records are not available. In our prior work, using Medicaid claims data, we have assigned primary care providers or determined primary provider of interest using a variety of methods to address plurality in care, including using most frequently see provider or most recently see provider.

• Characteristics of hospitals and health systems where diagnosis occurred and treatment was initiated and/or completed: hospital type (acute care, critical access), hospital ownership, hospital size (# of beds), hospital configuration (integrated system vs. non-integrated system) obtained through questionnaires and medical records abstraction and linked to external sources such as American Hospital Association data. Additional health system factors including hospital Commission on Cancer (CoC) accreditation of the primary treatment facility, of the follow-up care/treatment facility (if any), of the survivorship care facility (if any), and whether facility is a designated or affiliated with a National Cancer Institute (NCI)-designated cancer center. CoC accreditation status for each facility reported by the participant will be abstracted from the American College of Surgeons database85 and we will confirm NCI-designation or affiliation through web searches. We will also assess measures of health equity and hospital quality from the May 2021 Assistant Secretary for Planning and Evaluation (ASPE) Developing Health Equity Measures Report,86 including the CMS Office of Minority Health Mapping Medicare Disparities (MMD) Tool and the Centers for Medicare & Medicaid Services (CMS) HCAHPS and HEDIS Data,110 to identify areas of disparities between subgroups of Medicare beneficiaries (e.g., racial and ethnic groups) in health outcomes, utilization, and spending at the hospital and geographic levels.

• Primary and Secondary Outcome variables: We will also review medical records to confirm what treatment was recommended by participants' providers as well as what treatment participants ultimately received (primary outcome in main analysis). We will also explore secondary outcomes such as receipt of fertility-sparing vs. non-fertility-sparing treatment. We will be using using medical records we will assess timeliness of treatment. We will calculate the number of days between definitive diagnosis date and date of initiation of primary treatment (from medical records).

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.

ACHIEVE CSP ListofRegistryVariables v. 06.14.24 CLEAN.docx	List of Variables
ACHIEVE CSP ListofRegistryVariables v. 06.14.24 TRACKED.docx	List of Variables

RATIONALE

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

Inclusion of Women.

The study is restricted to individuals with a cervix and more specifically to racially/ethnically diverse individuals diagnosed with cervical cancer. We will assemble a cohort of approximately 672 non-Hispanic White (NHW), non-Hispanic Black (NHB), Hispanic/Latina, and Asian Pacific Islander (API) cervical cancer cases diagnosed in 2020-2025. Eligibility criteria include: 1) Individuals with a cervix diagnosed with cervical cancer in the past 18-24 months; 2) resident of New Jersey or California at cervical cancer diagnosis; and 3) able to speak and read English, Spanish, Creole (Haitian), or Mandarin (Chinese).

Inclusion of Minorities.

This study focuses on a racially/ethnically diverse sample of individuals diagnosed with cervical cancer. Guided by the NIMHD research framework, this mixed-methods study will leverage two population-based Surveillance, Epidemiology, and End Results (SEER) Program registries (New Jersey State Cancer Registry and Los Angeles Cancer Surveillance Program, which cover racially and ethnically diverse populations), to prospectively examine the impact of micro-, mezzo-, and macro-level factors – with an emphasis on macro-level factors – on receipt of guideline concordant treatment for and survival from cervical cancer. Given the estimated proportions of cervical cancer cases diagnosed by race and ethnicity recorded by the NJSCR and LACSP for 2017 through 2019, we estimate that approximately 35%, 14%, 37%, 12%, and 2% of our cohort will be non-Hispanic White, non-Hispanic Black, Hispanic, Asian American/Pacific Islander, and other (inclusive of American Indian/Alaska Native and multiracial) race and ethnicity categories, respectively.

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.)?

This statement is in the phone script:Even if you decide not to take part in this component of the ACHIEVE Study, your survey answers are very important to us, as no one can be substituted for you.

I am not sure what this means? If they decide not to participate what survey answers are you referring to?

01/07/2025 • Laura Lund, MA • *Not* Internal

This statement is in the phone script:["I don't have cancer. I don't know how you got my name."]:

Let me make sure I have the correct person again. Am I speaking with ¬¬_____? [Insists that they don't have cancer still] Okay, your name must be very similar to someone else we have in the cancer registry then.

This has the potential to disclose the cancer status of the named individual if you are not speaking to the correct individual. It would be better to ask them to give you their name (if they are willing) to check against your records instead of revealing the identity of someone in the registry.

01/07/2025 • Laura Lund, MA • *Not* Internal

Potential participants are told in the phone script: [If respondent wants to know how we got her name]:

Your name was obtained from the California Cancer Registry.

This is not exactly true for the follow up. It would be better to tell the that their name was originally obtained from the CCR for the Baseline survey, and that she is being contacted now because she enrolled in your study by completing a Baseline survey.

01/07/2025 • Laura Lund, MA • *Not* Internal

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

Study participants will be recruited through two population-based Surveillance, Epidemiology, and End Results (SEER) Program registries: New Jersey State Cancer Registry (NJSCR) and the Los Angeles County Cancer Surveillance Program (LACSP). Drs. Stroup (Co-I) and Liu (Co-I) serve as directors of the NJSCR and LACSP, respectively, and have established long-term, productive collaborations with Drs. Llanos and Tsui (MPIs).

Registry staff at NJSCR and LACSP, led by Drs. Stroup and Liu, respectively, will identify eligible cervical cases in the respective cancer registry databases and will initiate patient contact by sending eligible cases an introductory letter requesting their participation in the study, Informed Consent Form for the Baseline Survey, Baseline Survey, CCR brochure, and a postage paid return envelope, as well as instructions for completing the survey via other modes (i.e., online via REDCap link or by phone with the MPIs' research study staff). Only English, Spanish and Mandarin speaking or English, Spanish, and Chinese reading participants will be recruited from LACSP. Persons who don't speak English, Spanish, or Mandarin or can not read English, Spanish, or Chinese are ineligible for this study among LACSP participants.

In the first half of Year 1, staff from LACSP will identify eligible cases, review for completeness, and upload to the participant tracking databases. In the second half of Year 2 through Year 4, the baseline questionnaire will be administered. We have developed a standardized English Participant Recruitment Letter for eligible cases. Certified Spanish and Chinese Participant Recruitment Letter, Informed Consent Form for the Baseline Survey, and Preferred Language Sheet have been attached. The recruitment documents include the study objectives, implications of the research, and details of the survey and medical records abstraction protocol. We will use the registry variables NHIA and NAPIIA to identify persons with Spanish or Chinese identification, respectively, who will then receive study packets in both English and the specific ethnic languages. We will also include a "preferred language sheet" in dual-language packets asking them to complete the materials only in their preferred language. Registry staff will search for addresses where participant letters could not be delivered using Google and Lexis Nexis and will be re-sent.

Registry staff will make follow-up calls that will be made 2 weeks after the initial study packet is mailed to confirm if participants have received the packet and provide an opportunity to answer any questions about the study. This phone call also helps us to (a) legitimize the study mailing as a real study (not spam) (b) learn if the mailing was not received or they are not interested in participating and (c) gives the potential participant an opportunity to ask any questions and request a new packet to be mailed or send to an updated address, if they are interested. We have provided the English standard scripts for all recruitment phone calls and contacts that study staff will have with participants. We have also provided certified translations in Spanish and Chinese in a previous amendment after the

English version of the standard script is approved.

The average number of calls per patient will range from 6-8, however, additional follow-up phone calls may be conducted depending on the type of contact performed, conversations with the patient, and likelihood of response. The maximum number of phone calls will be 8. Phone calls will be staggered throughout the week, nights, and weekends, if necessary. Phone calls will be done in English, as well as in Spanish, Mandarin, and Creole (Haitian) (as needed with assistance from bi-lingual interpreters). Phone calls made to potential participants identified from LACSP will only be conducted in English, Spanish, and Mandarin.

Additionally, LACSP staff will send a baseline survey reminder letter with details on how to access the survey online to participants who do not respond after 4 weeks of initial contact. The inclusion of the mailing of a reminder letter for the baseline survey recruitment process was recommended by LACSP staff given its effectiveness in other LACSP recruitment studies. This also ensures consistency across the cancer registries engaged in this study as the New Jersey State Cancer Registry also mails a second set of materials after 4 weeks of initial contact.

Upon receipt of the signed Informed Consent Form and completed baseline survey, LACSP staff will send participants a second mailing consisting of their baseline survey incentive, an introductory letter requesting their participation in the medical release portion of the study, instructions for completing the Medical Release Consent Booklet, the Medical Consent Booklet which is a compilation of four documents (Instructions, consent form for participation in the Medical Records portion of the study, HIPAA Authorization, Healthcare Source Form), and a postage paid return envelope.

Upon receipt of the completed HIPAA Authorization, LACSP staff will send participants a third mailing consisting of their incentive for completing the previously listed forms and a thank you letter. Additionally, after receipt o the HIPAA Authorization and consent for medical records abstraction, members of the research and registry team will contact providers and healthcare facilities these patients have received care from to request medical records. They will send providers and healthcare facilities the Medical Records Physician Letter as well as the patient's signed HIPAA Authorization.

Registry staff will send eligible participants (those that have completed the Baseline Survey) the 12 Month Follow-up Survey recruitment packet requesting their participation in the 12 Month Follow-up survey portion of the study study approximately 12 months after completion of the baseline survey. This packet includes an introductory letter, written informed consent form for the 12 Month Follow-up Survey, 12 Month Follow-up Survey, and a postage paid return envelope, as well as instructions for completing the survey via other modes (i.e., online via REDCap link or by phone with the MPIs' research study staff). We have developed a 12 Month Follow-up Survey standardized English Participant Recruitment Letter and Informed Consent Form for eligible cases. Certified Spanish and Chinese 12 Month

Follow-up Survey Recruitment Letters and Informed Consent Forms for the 12 Month Follow-up Survey provided in an amendment after approval of the English versions. Participation in the Medical Records portion of the study is not a requirement to participate in the 12 Month Follow-up Survey portion of the study. Participants will be informed that they can decide to participate or not participate upon receipt of the 12 Month Follow-up Survey Recruitment Letter.

Staff from LACSP will wait 1 weeks from when the 12 Month Follow-up Survey study packet is mailed before initiating recruitment phone calls and will limit the number of calls to no more than 8.

LACSP staff also will send a 12 Month Follow-up Survey reminder letter with details on how to access the 12 Month Follow-up Survey online to participants who do not respond after 4 weeks of initial contact. The inclusion of the mailing of a reminder letter for the baseline survey recruitment process mirrors the Baseline Survey recruitment process for LACSP and NJSCR.

Upon receiving completed 12 Month Follow-up Survey, registry staff will mail the $50 incentive to participants.

Attach copies of all recruitment materials.

ACHIEVE LA 12M Survey Participant Recruitment Letter English v. 06.14.24.docx	Recruitment Materials
ACHIEVE LA 12M Survey Participant Reminder Letter English v. 06.14.24.docx	Recruitment Materials
ACHIEVE LA 12M Survey Recruitment Call Script v. 06.14.24.docx	Recruitment Materials
ACHIEVE LA 12M Survey Thank You Letter English v. 06.14.24.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Participant Recruitment Letter Chinese v. 08.01.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Participant Recruitment Letter Chinese v. 08.01.24 TRACKED.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Participant Recruitment Letter English v. 08.01.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Participant Recruitment Letter English v. 08.01.24 TRACKED.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Participant Recruitment Letter Spanish v. 08.05.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Participant Recruitment Letter Spanish v. 08.05.24 TRACKED.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Participant Reminder Letter English v. 11.05.24.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Recruitment Call Script v.5 CLEAN.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Recruitment Call Script v.5 TRACKED.docx	Recruitment Materials

ACHIEVE LA Baseline Survey Thank You Medical Records Letter Chinese v. 08.01.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Thank You Medical Records Letter Chinese v. 08.01.24 TRACKED.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Thank You Medical Records Letter English v. 08.01.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Thank You Medical Records Letter English v. 08.01.24 TRACKED.docx	Recruitment Materials
ACHIEVE LA Baseline Survey Thank You Medical Records Letter Spanish v. 08.05.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Medical Records Physician Letter v. 11.1.24.pdf	Recruitment Materials
ACHIEVE LA Medical Records Thank You Letter Chinese v. 08.01.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Medical Records Thank You Letter Chinese v. 08.01.24 TRACKED.docx	Recruitment Materials
ACHIEVE LA Medical Records Thank You Letter English v. 08.01.24 CLEAN.docx	Recruitment Materials
ACHIEVE LA Medical Records Thank You Letter English v. 08.01.24_TRACKED.docx	Recruitment Materials
ACHIEVE LA Medical Records Thank You Letter Spanish v. 06.14.24.docx	Recruitment Materials
ACHIEVE LA Preferred Language Sheet Chinese v. 06.14.24.docx	Recruitment Materials
ACHIEVE LA Preferred Language Sheet Spanish v. 06.14.24.docx	Recruitment Materials

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.
Cancer registry staff at NJSCR and LACSP will identify all eligible cases. Individuals must meet the eligibility requirements, which are: 21-79 years, with known age at diagnosis; diagnosed between January 1, 2020 and December 31, 2025; alive at least 3 months post-diagnosis. Case exclusion criteria: diagnosed by autopsy or death certificate only.

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.
Registry staff will mail incentive payments in the form of gift cards ($50) to participants' home address after they return their completed Informed Consent Form for the Baseline Survey and baseline questionnaire. Along with the baseline incentive, participants will receive a thank you letter that introduces the medical records portion of the study, including an Informed Consent Form for participation in the Medical Records portion of the study, HIPAA authorization, and healthcare source form for participants to complete. Participants will be informed that they can decide to participate or not participate upon receipt of the medical records abstraction letter. Upon receipt of signed Informed Consent Form for participation in the Medical Records portion of the study and completed HIPAA authorizations for medical records release and healthcare source forms, registry staff will mail payments ($25) to participants' home address. Registry staff will send an introduction letter to the 12-month follow-up and the 12-month follow-up (F/U) questionnaires to all enrolled participants approximately 12 months after completion of the baseline questionnaire. Participants will be informed that they can decide to participate or not participate upon receipt of the 12-month letter. Upon receipt of completed F/U questionnaires, registry staff will mail payments ($50) to participants' home address.

After discussing with our Community Advisory Board, we have increased the total amount a participant will receive from completing study activities from $100 to $125. We recognize that our surveys are lengthy and have increased the value to better compensate the participants for their time.

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 five-year study. Participants identified from LACSP will have the opportunity to complete two surveys over the study period, a baseline survey and a 12 month follow-up survey. Upon completion of the baseline survey, participants will be contacted to also provide authorization for medical records release. Participation in the medical records portion will not influence recruitment for the 12 month follow-up survey.

The baseline survey will take approximately 60 minutes to complete. We intend to pilot test the baseline survey with English, Chinese, and Spanish reading audiences and ensure that completion will take about 1 hour to complete. We will cut questions as needed if we find that average survey completion takes more than 1 hour. The follow-up survey will take approximately 30 minutes to 1 hour to complete.

The Healthcare Source Form for the medical records phase will take about 20 minutes to complete.

The total maximum approximate time commitment for participants identified from LACSP that have completed both surveys and Healthcare Source Form is 140 minutes (including the 12 Month Follow-up Survey).

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 known major risks associated with the proposed research. Some participants may feel that the information collected during questionnaires are sensitive or potentially embarrassing. All participants will be informed that their answers will be kept confidential and that they may refuse to answer any question that makes them uncomfortable. Breach of confidentiality is an additional risk. Data protection measures will be taken to minimize risk of breach of confidentiality. All research team members will also be trained in human subjects' protections and HIPAA regulations. In addition, analytic datasets will be stored on password protected drives by study identification number only. Further, external researchers requesting access to the data will be required to sign a data sharing agreement to protect the confidentiality of the data. All identifying information will be removed from shared data, and additional information will be redacted as needed to prevent deductive identification of individuals who are part of uncommon subpopulations. Therefore, a breach of confidentiality is highly unlikely.

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.

This research does not present major risks to participants and do not anticipate any adverse mental or physical effects. If participants experience distress, they are given the option to skip questions or decline participating. This language is repeated in multiple documents, such as the informed consent form for the baseline survey and baseline survey. They may also contact the PI with questions or concerns, whose contact information is provided on the consent form for the baseline survey and consent form for medical records abstraction. The English, Spanish, and Traditional Chinese Baseline Survey Consent Form and Medical Records Consent Form has been attached under the Study Procedures and Consent Forms sections.

INTERNATIONAL RESEARCH

Will this research occur outside of the United States or U.S. territories?

Check with client to see if they consider territories to be outside the U.S. or not, as this can vary between institutions.

No

LESS RISKY METHODS

Describe any less risky methods and why they are not being used.

This study was designed to be of minimal risk.

Participants may skip questions and participation is voluntary. Participants may decline participating which would carry the least risk.

BENEFITS

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

While the risks to the study participants whose data are included in this study are minor, there are also no direct benefits to the individuals who decide to participate in this study. The indirect benefit for participants of this study is the potential for answering important questions about the contributors of suboptimal cervical cancer treatment and poorer survival outcomes among individuals diagnosed with cervical cancer, which will be used to inform system-level practice and policy change to address the persistent inequities in cervical cancer survival.

JUSTIFICATION OF RISKS

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

This research presents minimal risks to participants in comparison to the potential benefit to society in the scientific knowledge gained.

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

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

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

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

HIPAA IDENTIFIERS

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

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

TRAINING PROCEDURES

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

All study staff are required to have current HIPAA, GCP, and Human Subjects certification while part of the study. The Cancer Surveillance Program requires individuals that use their data to complete yearly refresher trainings. Staff are also required to sign statements of confidentiality related to general use, security, and privacy.

STAFF VETTING PROCEDURES

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

All employees hired by University of Southern California undergo a background check.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

This is a statement from the state agency or department you are receiving data from. It must be on that agency's/department's letterhead and should include both

1) *that the release of the desired data is legal and*

2) *that the entity is willing to release the desired data to you, the researcher. If you are not receiving data, this letter should indicate that you are supported.*

***For VSAC requests, if you do not have a Departmental Letter of Support (LOS)/Data Release, you may upload a copy of the Data Request Form (application) from the department to secure a review for the upcoming cycle. The protocol will not be approved until the LOS is uploaded to the protocol.*

Please also review the CPHS Statement for Birth and Death Data.

CPHS_LOS_Tsui, J.docx.pdf Department Letter of Support

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

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

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

All data will be kept on secured servers and not released to any authorized person or entity. Dr. Tsui and the Co-Investigators will not release data or any other purpose by signing the CCR's Appendix 3.

CONFIDENTIALITY OF PUBLISHED DATA

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

If information from this study is published or presented at scientific meetings, participants' name and other personal information that could possibly be used to identify an individual subject will not be used.

DATA REQUEST JUSTIFICATION

Provide adequate justifications for the quantity of the data, the years and the variables being requested. Have you requested no more than the minimum necessary data to perform the research?

We have described our need for many of the data fields being requested in the study procedures and have copied our response in this form as well. This 5-year NIH funded study focuses understanding social, structural, and health system-level influences on treatment and survivorship outcomes among underserved women diagnosed with cervical cancer. No studies have systematically examined how intersectionality of multilevel factors – including indicators of structural inequities and racism – impact cervical cancer outcomes, a disease that is preventable but persistently overburdens marginalized communities. Thus, a rigorous, comprehensive analysis of individual-, area, and health system-level factors that predict suboptimal treatment receipt and cervical cancer survival, such as this project, will yield critical knowledge to inform actionable health care delivery practice change and policies to close persistent disparities in care quality and survival. We have added more details to justify our intersectional approach to this understudied area:

Historically, race has been used as a predictor of poorer outcomes at the individual-level or as a confounder (at the population-level) in public health research, rather than as a proxy for a myriad of health risks resulting from existence in sociopolitical systems of power and oppression based on race. Limiting our understanding of racism to interpersonal and psychosocial dimensions fosters the notion that race and racism are personal constructs, and obscures and absolves racism's systemic roots. To promote health equity, population health research must clearly operationalize structural racism, accounting for its multi-dimensional nature, whereby internalized, interpersonal, and institutional levels interact to influence a range of health outcomes. The problem with existing structural racism metrics is that they focus on single dimensions of structural racism, which don't convey how many institutions and industries contribute to the observed health disparities. Multiple dimensions of structural racism (operationalized in this study as social and neighborhood-level deprivation largely due to long-term impacts of civil rights laws, legal racial discrimination, economic deprivation, police violence/over-policing, and/or residential segregation and housing discrimination) may follow a common path (e.g., education inequity leads to employment inequity) or may interact thereby having cumulative effects on health (e.g., education inequity among inhabitants of segregated areas). To adequately address structural factors, and move beyond standard individual demographic factors, our study requires measurement of intersectional and multilevel influences, including immigration, police encounters, and neighborhood concerns. We base these measures off other peer-reviewed studies, police encounter scales from other population-based research, and neighborhood concerns from scales in the PhenX Toolkit. Our established research team, including partners at the cancer registries and co-investigator Hughes-Halbert senior investigator and Director of Cancer

Equity at USC Norris, will work together to ensure confidentiality and data protection.

For evaluating the association of micro-, mezzo-, and macro-level social and structural factors on screening history, diagnostic barriers and receipt of guideline-concordant treatment for invasive cervical cancer: We will first examine the distribution of each social and structural factor using histograms, boxplots, and means and standard deviations for continuous variables, and bar graphs and frequencies for categorical and ordinal variables. The association of each micro-level social and structural factor on the primary outcome (receipt of guideline-concordant treatment) will be assessed using logistic regression model. The association of each mezzo- or macro-level factor will be assessed using mixed effects logistic regression model with community or healthcare system as random intercepts to consider the potential for clustering effects. Models will include confounders – identified using directed acyclic graphs (DAGs), and factors strongly predictive of the outcome but unaffected by exposure – to improve model fit. Significant confounders will be included in mixed effects multivariable logistic regression models to evaluate the common impact of micro-, mezzo-, and macro-level factors on the primary and secondary outcomes. We will assess the impact of primary predictors of interest (i.e. on the outcomes one at a time), adjusting for potential confounders. To deal with the multiple testing issues, the Benjamin-Hochberg procedure will be used to control the false discovery rate. To study the common effects of independent variables on clinical outcomes, we will include all independent variables in the regression model, adjusting for potential confounders. We will select strategies for handling missing data based on the type of data missing and extent of missingness. If significant proportions (>15%) of data are missing for any given variable, multiple imputation will be used. Min to add multicollinearity here: We will use elastic net models (i.e., combination of LASSO and Ridge regression) to handle potential collinearity among independent variables and confounders, as well as to identify important independent variables.

For evaluation of the association of micro-, mezzo-, and macro-level social and structural factors on cervical cancer outcomes: We will assess the impact of each micro-level factor on overall survival and cervical cancer-specific survival using Cox model. For each of the mezzo- and macro-level factors, Cox frailty models will be used to consider the community or healthcare system random effects. Multivariable Cox or Cox frailty models will be used to adjust for confounders and evaluate the common effects of all social and structural risk factors. For patient-reported outcome scores, linear regression and mixed effects linear models will be used to assess the effects of the risk factors on each outcome. We will explore stratified analyses by stage (locally advanced vs. early-stage) to examine between-group differences in the associations of interest.

We understand providing the follow-up questionnaire will be informative for the review committee. However, the follow-up survey does not get administered until 12 month following baseline survey completion. We addressed this in the study procedures and have copied our response in this form as well. We do not have the follow-up survey ready at this time, but

fully anticipate providing this for CPHS review and approval well in advance and at least 6 months prior to our timeline for initiating follow-up survey administration. We have included a table in the study procedure section that includes how the planned follow-up survey content compares to the baseline questionnaire. In brief, the follow-up survey will continue to ask questions micro-, mezzo-, and macro-level factors, but will focus more on survivorship care periods instead of screening, diagnosis, and acute treatment experiences of care.

We have described the data to be abstracted from the medical record in the database details and have copied our response in this form as well. We will collect provider information in the baseline survey and also use relevant place of service codes from LACSP to identify providers and obtain provider characteristics where feasible (specialty, location etc). We have added a description of the medical records abstraction fields in the study protocols and database details. Briefly, we will use medical records in addition to cancer registry information and patient surveys, to obtain provider and health system characteristics. At the healthcare system-level, we are interested in the impact of the following factors:

• Characteristics of providers involved in cervical cancer diagnosis and treatment: specialty (gynecologic oncologist, gynecology/obstetrics, other specialty), practice type (community hospital affiliated, academic medical center, private practice), racial/ethnic concordance with patient (yes vs. no). We will use medical records as the primary data source to obtain provider characteristics where possible, and then use patient report through surveys or cancer registry data if medical records are not available. In our prior work, using Medicaid claims data, we have assigned primary care providers or determined primary provider of interest using a variety of methods to address plurality in care, including using most frequently see provider or most recently see provider.

• Characteristics of hospitals and health systems where diagnosis occurred and treatment was initiated and/or completed: hospital type (acute care, critical access), hospital ownership, hospital size (# of beds), hospital configuration (integrated system vs. non-integrated system) obtained through questionnaires and medical records abstraction and linked to external sources such as American Hospital Association data. Additional health system factors including hospital Commission on Cancer (CoC) accreditation of the primary treatment facility, of the follow-up care/treatment facility (if any), of the survivorship care facility (if any), and whether facility is a designated or affiliated with a National Cancer Institute (NCI)-designated cancer center. CoC accreditation status for each facility reported by the participant will be abstracted from the American College of Surgeons database85 and we will confirm NCI-designation or affiliation through web searches. We will also assess measures of health equity and hospital quality from the May 2021 Assistant Secretary for Planning and Evaluation (ASPE) Developing Health Equity Measures Report,86 including the CMS Office of Minority Health Mapping Medicare Disparities (MMD) Tool and the Centers for Medicare & Medicaid Services (CMS) HCAHPS and HEDIS Data,110 to identify areas of disparities between subgroups of Medicare beneficiaries (e.g., racial and ethnic groups) in health outcomes, utilization,

and spending at the hospital and geographic levels.

• Primary and Secondary Outcome variables: We will also review medical records to confirm what treatment was recommended by participants' providers as well as what treatment patients ultimately received (primary outcome in main analysis). We will also explore secondary outcomes such as receipt of fertility-sparing vs. non-fertility-sparing treatment. We will be using using medical records we will assess timeliness of treatment. We will calculate the number of days between definitive diagnosis date and date of initiation of primary treatment (from medical records).

LIMITATIONS TO DATA ACCESS

Indicate if access to data is limited only to those with a need to know for purposes of implementing or evaluating the research.

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

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

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

Cells with under 11 cases will be suppressed in any publication.

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*

ACHIEVE_Jennifer Tsui - Cervical Cancer Inequities.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.
Personal identifiers, such as name, will be removed and a de-identified research file will be generated. Study IDs will be generated for each participant.

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.

We will use cross cut shredding to ensure that PID in paper form is disposed of in a confidential method.

FAXING

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

We do not intend to use fax machines. In the event it is needed, fax machines are in secure areas and no faxes with PID will be sent or received.

MAILING

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

Any mailing of PID will be sealed and protected. There will be no mailings of 500 or more individually identifiable records of PID.

ELECTRONIC STORAGE

State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will ever be left unattended in cars or other unsecured locations.

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

PHYSICAL STORAGE

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

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

SERVER SECURITY

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

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

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Identifiers will be stored separately from analysis data.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID will be destroyed.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

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

FIPS 140-2 COMPLIANCE: WORKSTATIONS

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

All workstations have FIPS 140-2 encryption.

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 laptops have FIPS 140-2 encryption.

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 have FIPS 140-2 encryption.

SECURITY PATCHES

Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

All computers are updated daily with security software. Laptops are updated frequently with security software.

PASSWORD CONTROLS

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

Sufficiently strong passwords are in place.

ELECTRONIC SECURITY CONTROLS

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

Yes, these security controls are in place.

FIPS 140-2 COMPLIANCE: ELECTRONIC TRANSMISSION

Explain whether all transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.

No PID will be transmitted outside of our secure internal network.

INTERNET ACCESSIBILITY

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

No, PID will be no accessible to the internet.

DISPOSING OF PID

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

Physical destruction or sufficiently secured wiping of PID 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.

As reflected in our most recent response to the Deferred Approval Letter dated February 5, 2024, we have uploaded the the Informed Consent Form for the Baseline Survey for participants to complete written consent upon receiving the baseline survey recruitment packet.

Participants will be provided an Informed Consent Form for the Baseline Survey as part of the baseline survey recruitment packet (first contact) mailed to their address. The Informed Consent Form for the Baseline Survey informs the participant what participating in the baseline survey entails and how to consent to participating in the baseline survey. The recruitment letter and instructions for completing the survey provides study information and instructs the potential participant to review and provide written consent prior to completing the survey. The standard English Informed Consent Form for the Baseline Survey has been attached. Certified Spanish and Chinese Informed Consent Forms for the Baseline Survey have been attached.

Instructions for completing the Informed Consent Form for the Baseline Survey are listed as the first step on the instructions for completing the baseline survey. Participants who choose to continue with paper survey are requested to read and sign the consent form prior to starting the survey. Those that choose to complete the survey online will be able to access the informed consent form on REDCap prior to beginning the survey. Those that would like to complete the survey over the phone are instructed to contact a study team member for additional instructions for providing consent. Our baseline survey recruitment telephone script provides a standard script for study staff to ask participants for their preference for providing written consent. Participants will be provided the option to receive the link to the Informed Consent Form phone via text or email prior to completing the Baseline Survey by telephone.

Upon receiving participants' completed written Informed Consent Form and completed baseline survey, CSP staff will mail the participant incentive for baseline survey completion and the Medical Record Consent Booklet. The booklet will include the Informed Consent Form for participation in the Medical Records portion of the study. Participants are instructed to complete the Informed Consent Form for Medical Records prior to completing the HIPAA Authorization form and Healthcare Source Form. They are also instructed to mail back the Informed Consent Form for Medical Records, HIPAA Authorization form, and Healthcare Source Form. Certified Spanish and Chinese Informed Consent Forms for Medical Records have been attached.

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.

ACHIEVE LA Baseline Survey Consent Form English v. 06.14.24 CLEAN.docx	Consent Form
ACHIEVE LA Baseline Survey Consent Form English v. 06.14.24 TRACKED.docx	Consent Form
ACHIEVE LA Medical Records Consent Form English v. 06.14.24 CLEAN.docx	Consent Form
ACHIEVE LA Medical Records Consent Form English v. 06.14.24 TRACKED.docx	Consent Form

TRANSLATED DOCUMENTS

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

ACHIEVE LA Baseline Survey Consent Form Chinese v. 06.14.24.docx	Consent Form
ACHIEVE LA Baseline Survey Consent Form Spanish v. 06.14.24.docx	Consent Form
ACHIEVE LA Medical Records Consent Form Chinese v. 06.14.24.docx	Consent Form
ACHIEVE LA Medical Records Consent Form Spanish v. 06.14.24.docx	Consent Form

TRANSLATOR

Provide a copy of the curriculum vitae of the translators(s) and/or proof of certification of the translation firm.

CPHS may reject poorly written documents or documents from translators lacking adequate proof of training or expertise. For studies using documents translated into Spanish, the translation should use formal language.

LA Translation Certifcation.pdf Translator Curriculum Vitae

HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

Yes

HEALTHCARE PROVISIONS

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

Yes

BILLING/ELIGIBILITY

If the study involves the provision of healthcare, will a health insurer or billing agency be contacted for billing or eligibility?

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

Yes

HIPAA WAIVER

Are you requesting a waiver or alteration of HIPAA authorization?

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

No

HIPAA AUTHORIZATION FORM

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

ACHIEVE Medical Records HIPAA Authorization v.4_CLEAN.docx	HIPAA Documents
ACHIEVE Medical Records HIPAA Authorization v.4_TRACKED.docx	HIPAA Documents

Amendment Changes

List the pages and questions that have been changed.

1) 12 MONTH FOLLOW-UP SURVEY AND RECRUITMENT MATERIALS: We are requesting the approval of the English version of the 12 Month Follow-up Survey and Recruitment Materials. Members of our participant cohort will be requested to participate in Step 3 of the study, the 12 Month Follow-up Survey. LACSP will oversee all components of the 12 Month Follow-up Survey recruitment process for cases diagnosed with cervical cancer in Los Angeles. Once approvals for these materials are received, we will request for Spanish and Traditional Chinese translation and submit at a later amendment for approval. We have uploaded the 12M Follow-up Survey, invitation letter, reminder letter, consent form, survey instructions, and participation thank you letter to the Study Procedures section of the Project Details page. The 12M Follow-up Survey recruitment documents (invitation letter, reminder letter, thank you letter, and call script) have also been uploaded to the Recruitment Details section of the Study Population page.

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

USC-S02A00(GG017315-01)(22-0867)__G17751.pdf Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

ACHIEVE R01- CPHS Cover Letter_Tsui Signed.pdf Cover Letter

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

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

California Department of Public Health: Los Angeles Cancer Surveillance Program - California Cancer Registry