

CPHS Full Board Review - Amendment

Assessing Cervical Cancer Healthcare Inequities in Diverse Populations: The ACHIEVE Study Protocol # 2023-117

June 5, 2026



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Study Purpose



The ACHIEVE Study is a multi-site NIH-funded study, recruiting cancer survivors from LACSP and NJSCR, that examines how social and structural factors contribute to inequities in cervical cancer treatment and outcomes.

Specific aims

1. Evaluate how **social and structural factors** influence receipt of **guideline-concordant treatment**.
2. Evaluate how **social and structural factors** influence **cervical cancer outcomes**.
3. Identify **strategies to improve equitable cervical cancer care and outcomes** through stakeholder engagement.

Study Participants

Eligibility Criteria:

1. Identified from the **Los Angeles Cancer Surveillance Program** and the **New Jersey State Cancer Registry**
2. Diagnosed with **invasive cervical cancer** between 2021–2024
3. Age **21–79 years** at diagnosis
4. Able to complete study materials in **English, Spanish, or Traditional Chinese**

Target recruitment 960 survivors



CPHS amendment overview



1. Revise consent procedures to be consistent across both registry sites by aligning LACSP process with NJSCR process:

- Participants provided with a study information sheet.
- Participants will indicate their consent to participate by completing and returning the study surveys.

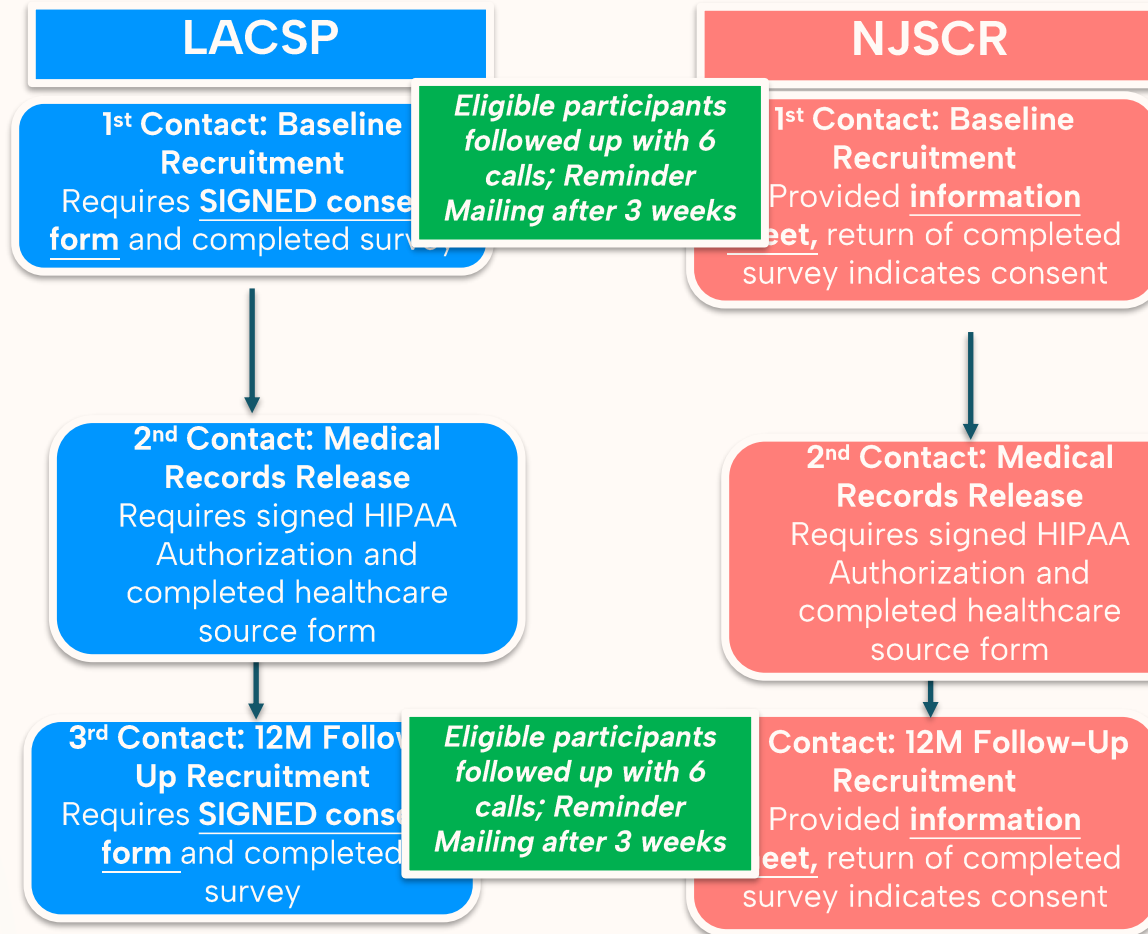
2. Reduce survey length to reduce participant burden:

- We propose a shorter baseline survey (16% fewer items)
- We propose a shorter 12M follow-up survey (35% fewer items)

Overall goal:

To improve participation, representativeness, and scientific quality while maintaining strong participant protections.

Data Collection and Recruitment Process



LACSP – 42 pages total

NJSCR – 37 pages total



The following documents have been provided to you in both English and Spanish. Please complete one version in your preferred language. Thank you.

Study Coordinators:
Yessenia Carranza (323-865-0013 English or Spanish)
Belle Lele (326-780-9880 English)

Las siguientes documentaciones están disponibles en inglés y en Español. Por favor, complete una versión en su idioma preferido. Muchas gracias.

Las Coordinadoras del Estudio:
Yessenia Carranza (323-865-0013 Español o inglés)
Belle Lele (326-780-9880 inglés)


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Instruction for completing the baseline survey

There are two steps to participating in the Assisting Cancer Control Centres' Integration to Birmingham Partnership: THE KCCRC Study

For your convenience, there are three ways for you to participate in the baseline survey:

1. **Online registration**
 - Return and sign the enclosed Informative Consent Form – (BIRMINGHAM SURVEY)
 - Fill out and email back your survey
 - Mail the signed Informative Consent Form and completed survey back to us using the enclosed **prepaid envelope**
2. **Online registration**
 - Return and sign the Informative Consent Form – (BIRMINGHAM SURVEY) and use the QR code to access the online survey
 - Fill out and email back your survey
 - Mail the signed Informative Consent Form and completed survey back to us using the enclosed **prepaid envelope**
3. **Offline registration**
 - After signing the Informative Consent Form, please fill out Name and contact and email to ccrc@bham.ac.uk
 - Return the Informative Consent Form to the research team and contact team member **Elaine Dore** at elaine.dore@bham.ac.uk to receive a link to access the online survey

Once you complete the survey, you will be invited to participate in the rest of the study. This will involve completing an online survey and a focus group on your participation in the rest of the study. The focus group will discuss your experience of the medical research part of the study. This will enable us to participate in the rest of the study of the study. If you have any questions or concerns about the study, please email or call our study team coordinator Elaine Dore at 0121 454-4933 or 4933 or via email at elaine.dore@bham.ac.uk

Version 0.01, 16-10-2020
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GOOD NEWS! Study materials are also available in Spanish and Chinese. Please call at (800) 541-7402 if you would like these documents in Spanish or Chinese so that you can participate. All information, no matter how large or small, can make a difference. Thank you!

¡BUENAS NOTICIAS! Los materiales del estudio también están disponibles en español y chino. Llame al (800) 541-7402 si desea estos documentos en español o chino para poder participar. Toda información, por grande o pequeña que sea, puede marcar la diferencia. ¡Gracias por su ayuda!

好消息！ 研究材料也有中文和西班牙文版本。中文及西班牙文版本，如蒙惠顧，請電 (800) 541-7402 索取。中文或英文資料可透過網路或來電索取。感謝您！(800) 541-7402 索取。任何資訊，無論大小，皆能產生影響。感謝您的協助！

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Recruitment letter

Survey Instructions (1 page)

Language Options Sheet

Recruitment letter

Informal Contact: NCI/NIH SURVEY
1. Researcher's contact information
TITLE of Study: Assessing Cancer Researcher's Health Impacts in Diverse Populations: The ACTIVE Study
Principal Investigator: Columbia University Professor: Adam L. Pearce, MD, MPH and
Associate Professor: Jennifer Tai, MD, MPH
Phone Number: (212) 305-7558
Email address: adam.pearce@columbia.edu
adam.pearce@nyu.edu
adam.pearce@nyu.edu
University of Southern California (USC): Principal Investigator: Jennifer Tai, MD, MPH
Email address: jen.tai@usc.edu
Department: Department of Medicine, Department of Population and Public Health Sciences
Department of Preventive Medicine, USC Keck School of Medicine
Email address: jen.tai@usc.edu

Before you can answer, please read the informed consent form carefully. This explains why we are doing this research, what we are going to do, and what you can expect to happen to you as a result of your taking part in this research. You will be asked to sign a statement saying that you understand what we are asking you to do and that you agree to participate in this research study. You will not be paid for participating in this research study. You will not be paid for participating in this research study.

2. Why are we doing this study?

We are doing this research study to learn more about the impact of social and structural factors on cancer prevention, treatment and survival outcomes. You want to learn more information about how these factors affect cancer prevention, treatment and survival outcomes and please to answer the pertinent questions in our survey cancer research in the United States.

Are we asking you to participate in this study because you are interested in this study?

We are asking you to participate in this study because you were invited by the New Jersey State Cancer Registry (NJSCR) of the Los Angeles County Cancer Surveillance Program (LACSP) as part of the National Cancer Institute (NCI) Cancer Researcher's Health Impacts in Diverse Populations (ACTIVE) study. The NCI Cancer Researcher's Health Impacts in Diverse Populations (ACTIVE) study was created to get information on how cancer researchers in the US feel the most and least about their work. Every cancer researcher diagnosed in Los Angeles County is required by law to be registered in the NCI Cancer Researcher's Health Impacts in Diverse Populations (ACTIVE) study. We are now asking you and other researchers registered on the Institutional Review Board (IRB) for the NCI Cancer Researcher's Health Impacts in Diverse Populations (ACTIVE) study.

INFORMATION



Assessing Cancer Healthcare Inequities in Diverse Populations: The ACHIEVE Study

BASELINE QUESTIONNAIRE

Thank you for participating in the Assessing Cancer Healthcare Inequities in Diverse Populations (ACHIEVE) Study to understand cervical cancer treatment and outcomes in New Jersey. We will use the information you provide to help us learn more about the barriers that you experience when you seek care for your cervical health and to help us determine if you are getting the care you need. Your participation is voluntary, and you can stop participating at any time without any negative consequences. Your information will be kept confidential and used only for the purposes of the study. We will appreciate your time and contribution to this study.

Instructions:

1. Please use **NOT** with your name on any of the questionnaire pages.
2. Please try to answer each question as accurately as possible. If you don't feel comfortable answering a question, just skip it and go to the next one.
3. Enter the date and time you started the questionnaire in the space provided below.

Date questionnaire was started:

M	M	D	Y Y Y Y

Time questionnaire was started:

H	H	M	S

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Baseline questionnaire V1 2/20/2024






Study Information

TITLE OF STUDY: Assessing Clinical and Psychological Outcomes in Chronic Pain Patients: The APACHE Study

Principal Investigator: Amanda K. Lewis, PhD, NPS, CMAA, University, Jarrow, Tyne, The APACHE Study

Study Sponsor: The University of Northumbria

Study Description: This study is a study of informed consent process will provide you information to help you decide whether or not you wish to take part in the study. The study is intended to collect information to help us to improve the way we deliver research.

What is the purpose of the study and what are the aims of the study?

Objectives of the study: The aim of the study is to assess the impact of the APACHE Study on the lives of people with chronic pain. The study will also assess the impact of the APACHE Study on the lives of people with chronic pain. The study will also assess the impact of the APACHE Study on the lives of people with chronic pain.

What are the aims of the study?

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What are the aims of the study?

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PARTICIPANT ID: _____



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

BASELINE QUESTIONNAIRE

Thank you for participating in the Assessing Cervical Cancer Healthcare Inequities in Diverse Populations (ACHIEVE) Study to understand cervical cancer treatment and outcomes in New Jersey and California. The baseline questionnaire will take you about 10 minutes to complete. We will use the information you provide to help us understand the barriers to cervical cancer care and how we can best address them. We have the option to skip any question you don't feel comfortable answering. Your responses are confidential and will not be shared with anyone outside of the research team (or contacted information). We truly appreciate your time and contribution to this study!

Instructions:

- Please do NOT write your name on any of the questionnaire pages.
- Please try to answer each question as accurately as possible. If you don't feel comfortable answering a question, just leave it empty for the next time.
- Enter the date and time you started the questionnaire in the space provided below.

Date questionnaire was started: / / : :

Time questionnaire was started: : :



Baseline questionnaire ID: Z00002024

Consent Form (5 pages)

Survey

Information sheet (2 pages)

Survey

Recruitment by Registry Site (Sept 2024-May 2026)



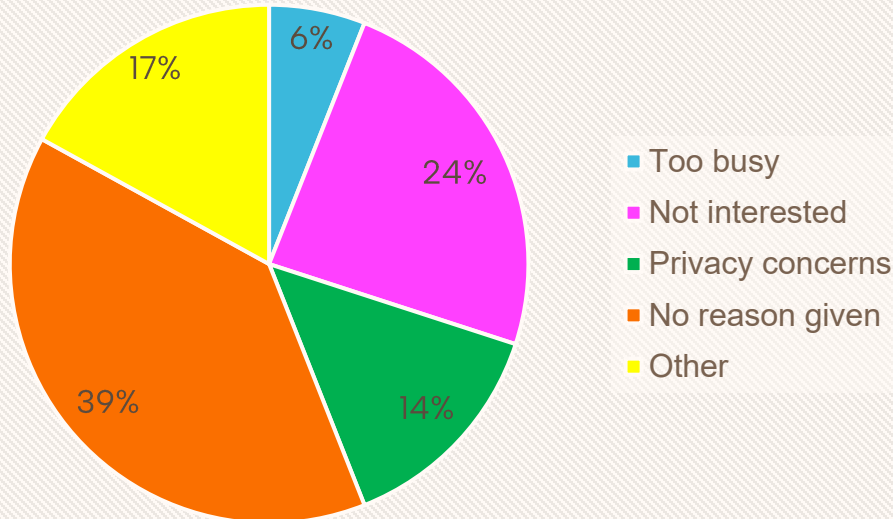
	Total	LACSP	NJSCR
BASELINE RECRUITMENT	N (%)	n (%)	n (%)
Eligible cases contacted (dx years 2021-23)	1834	965	869
Active refusal	175 (9.5)	116 (12.0) ↑	59 (6.8)
Completed baseline surveys (Response Rate)	343 (18.7)	148 (15.3) ↓	195 (22.4)
12M FOLLOW-UP RECRUITMENT	N (%)	n (%)	n (%)
Eligible cases for follow-up contacted to date (dx years 2021-22)	196	76	120
Active refusal	7 (3.6)	1 (1.3)	6 (5.0)
Completed 12M follow-up surveys (Response Rate)	117 (59.7)	50 (65.8) ↑	67 (55.8)



LACSP baseline active refusal cases

Active Refusals n = 148 (15.3%)

Documented Reasons for Refusal



Among 'Other' Reasons

- Survey length; Fear of re-living cancer or other emotional struggles ; Not feeling well; Unable to focus on survey; Financial questions intrusive
- Thought study was a scam
- General overload of mail, spam calls, emails in day-to-day life

Input and support from ACHIEVE Community Advisory Board (CAB) & Partners



- Reduces concerns about privacy, mistrust, and signing formal documents
- Creates a more participant-centered and culturally responsive recruitment process
- Reduces possible stigma-related concerns associated with cervical cancer and sexual health
- Supports more equitable participation and broader representation of survivor experiences





Summary

- Lower response rates in LACSP (**15.3% vs 22.4%**) increases selection bias and limits representativeness in Los Angeles participants
- Use of information sheet only in NJSCR did not result in reporting of adverse events
- Simplified consent procedures will reduce participant burden & worry about signed documents
- More representative recruitment supports ACHIEVE's goals of understanding survivorship disparities across diverse populations

CPHS amendment overview



7. Revise consent procedures to be consistent across both registry sites by aligning LACSP process with NJSCR process:

Common Rule:

- (1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:
- (i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
 - (ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

Overall goal:

To improve participation, representativeness, and scientific quality while maintaining strong participant protections.