CPHS Full Board Review - Amendment

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

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Columbia University Irving Medical Center · NJ Health New Jersey Department of Health, New Jersey State Cancer Registry · Rutgers Health, Rutgers Cancer Institute · Los Angeles County Cancer Surveillance Program · Keck School of Medicine of USC

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.

Funded by NIH/NIMHD grant R01MD018250 (2023-2027).

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:

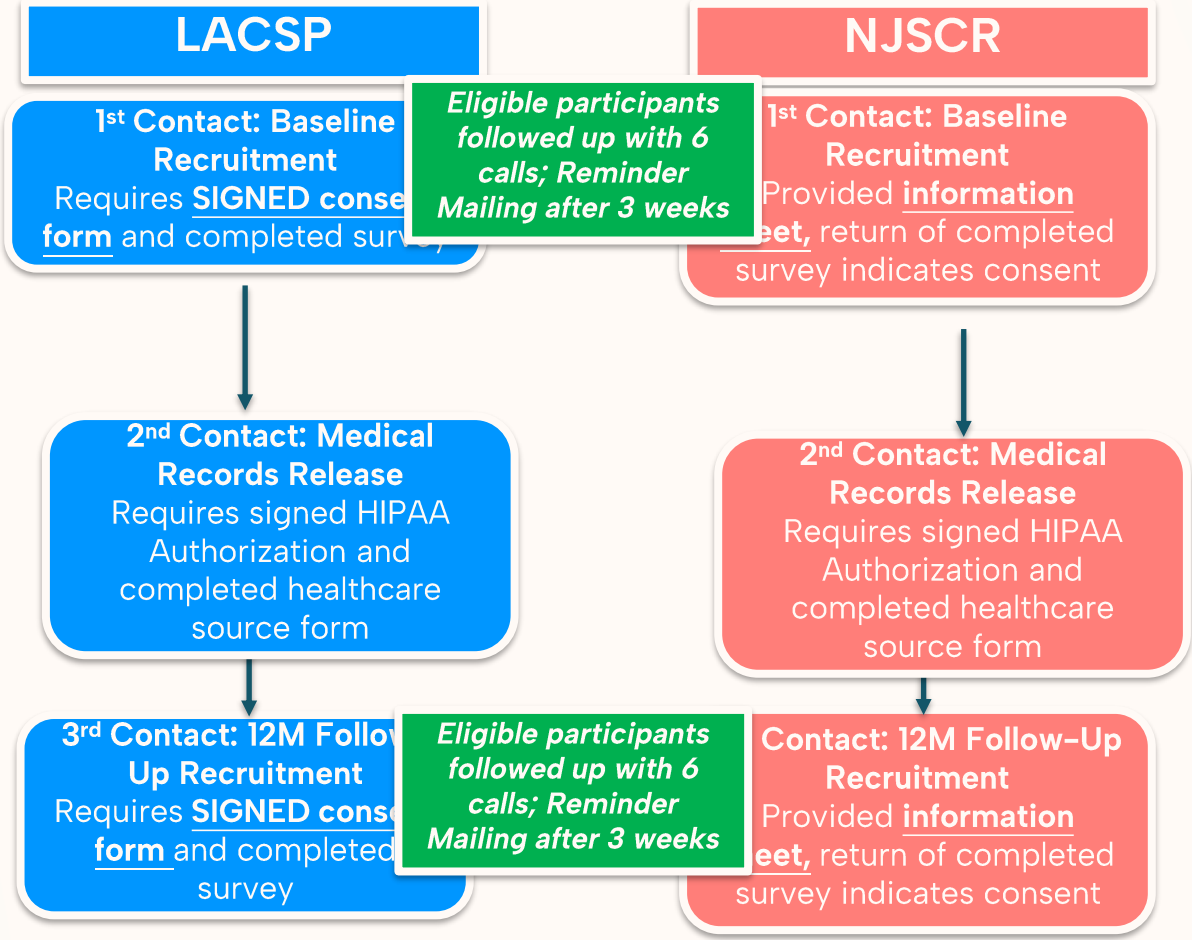
- Participants provided with a study information sheet.
- Participants will indicate their consent to participate by completing and returning the study surveys.

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



Baseline recruitment packet

LACSP – 42 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 (323-865-6013 English or Spanish)

Belle Lee (626-780-9880 English)

Los siguientes documentos están disponibles en Inglés y en Español. Por favor, complete una versión en su idioma preferido. Muchas gracias.

Las Coordinadoras del Estudio:

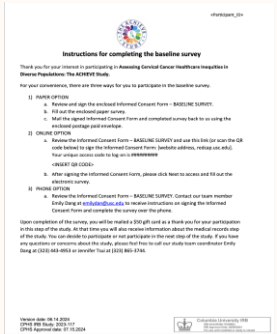
Yessenia Carranza (323-865-6013 *Español o Inglés*)

Belle Lee (626-780-9880 *Inglés*)

Language Option Sheet

Keck School of Medicine of USC

Recruitment letter

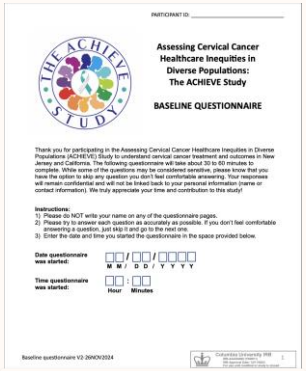


Instructions for completing the baseline survey

Survey Instructions (1 page)

Informed Consent Form – BASELINE SURVEY

Consent Form (5 pages)



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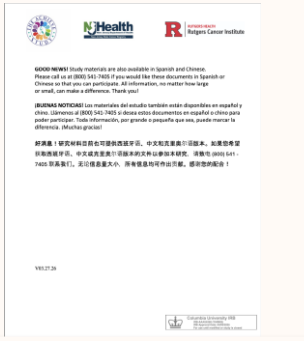
BASELINE QUESTIONNAIRE

Survey

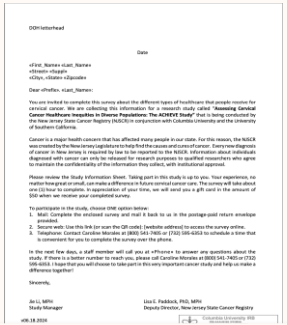
NJSCR – 37 pages total



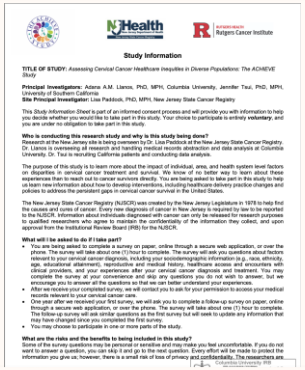
GOOD NEWS! Study materials are also available in Spanish and Chinese. Please call us at (800) 541-7405 if you would like these documents in Spanish or Chinese so that you can participate. All information, no matter how large or small, can make a difference. Thank you!

¡BUENAS NOTICIAS! Los materiales del estudio también están disponibles en español y chino. ¡Llámenos al (800) 541-7405 si desea estos documentos en español o chino para poder participar. Toda información, por grande o pequeña que sea, puede marcar la diferencia. ¡Muchas gracias!

Language Options Sheet

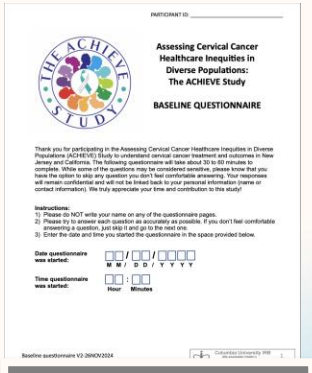


Recruitment letter



Study Information

Information sheet (2 pages)



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BASELINE QUESTIONNAIRE

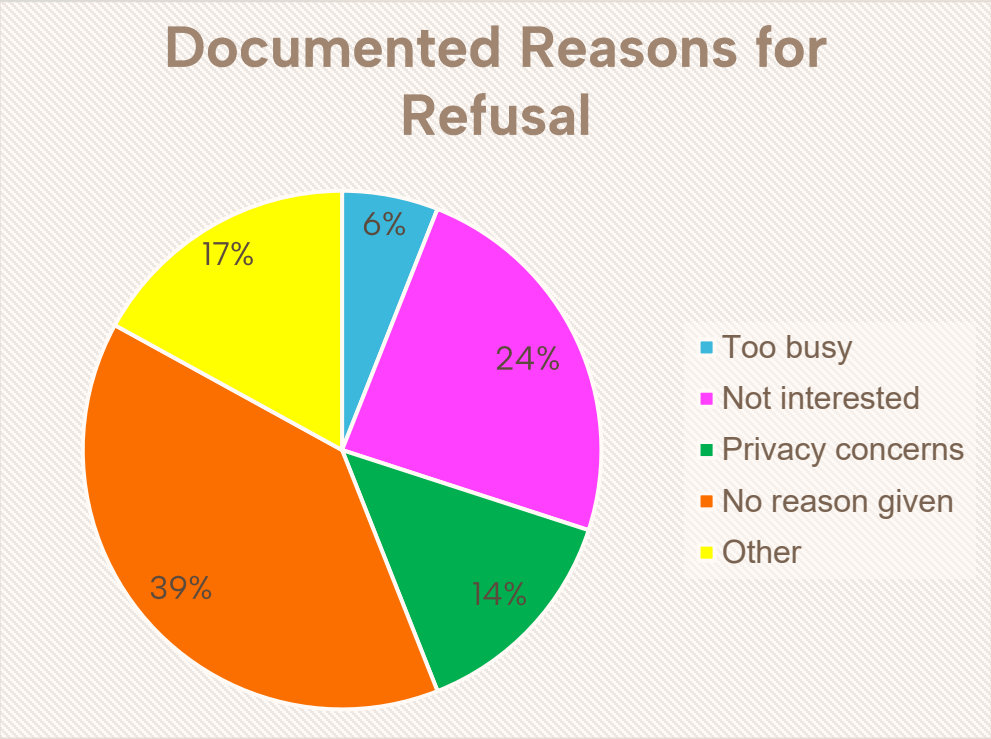
Survey

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%)



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

1. **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.