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Consenter Race and Community Resemblance Drive Clinical Trial Enrollment Among Women of Color: A Mixed-Methods Breast Clinic Study

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ABSTRACT

Clinical research is meant to serve all communities. For this reason, the National Cancer Institute expects each cancer center to recruit participants in numbers that reflect the cancer prevalence in their service regions. However, many centers do not achieve this balance. The individual who obtains consent for participation often interacts most closely with potential subjects. We proposed that the ethnic, racial, and linguistic background of the consenter could meaningfully influence a person's willingness to enroll. To test this, we conducted a mixed-methods study exploring how the cultural identity of the person obtaining consent might shape patients' decisions about joining a clinical trial. Between January 2018 and February 2020, 205 women attending our breast clinic were approached in sequence; 181 completed the survey. Of these, 94 (52%) identified as Northern European, non-Hispanic White (NE White), and 87 (48%) as Women of Color (WOC) — including Asian, Black, Hispanic/Latina, and Native American participants. Clear statistical differences emerged regarding how important the consenter's identity was in the decision to enroll. No NE White participant (0%, n = 0) considered the consenter's race relevant, compared with 11% (n = 9) of WOC respondents (p = 0.0009). Similarly, none of the NE White group valued having a consenter "who looked like people in my community, " while 12% (n = 10) of WOC respondents did (p = 0.0004). These outcomes indicate that the racial and ethnic background of the consenter can influence representation in clinical trials. Broader investigations are needed to determine whether this pattern applies elsewhere.

Keywords: Mixed-methods, Diversity, Inclusivity, Clinical research, Biomarkers

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Introduction

When participant recruitment lacks demographic breadth, trial findings cannot be reliably applied to wider populations [1-3]. At City of Hope, recruitment for our non-interventional and non-therapeutic studies closely paralleled the racial and ethnic composition of both our Duarte Breast Oncology Clinic and the Comprehensive Cancer Center's catchment zone. No population group was either under- or over-represented. This parity occurred even though we (1) offered no participant incentives, (2) did not oversample any racial or ethnic segment, and (3) provided no diversity training for our consent staff. The only plausible explanation was that the individuals obtaining consent reflected the same cultural variety as the Southern Los Angeles communities they served. This led us to speculate that the demographic mix among consenters might be directly tied to our success in enrolling diverse participants.

Typically, the Clinical Research Assistant (CRA)—the staff member responsible for consent—has the most frequent and personal contact with research subjects [4]. Building a sense of trust between the CRA and potential enrollees is essential for fair and inclusive recruitment. We reasoned that CRAs who can relate to participants from multiple backgrounds might encourage broader participation across ethnic lines.

Although many high-impact studies have examined the lack of diversity in clinical trial recruitment and have proposed potential remedies [5-7], almost none have explored how the identity of the person obtaining consent affects this issue.

To evaluate our hypothesis, we created a prospective population-based mixed-methods project assessing whether consent characteristics influence who joins clinical studies. The work focused on three non-interventional breast cancer trials at the City of Hope Comprehensive Cancer Center (COHCCC) and involved both a survey and personal interviews. We anticipated that individuals might be more open to participation when approached by someone who shared their appearance, language, or cultural understanding. This paper presents our findings on how a consenter's socio-cultural profile relates to decisions about research participation.

Materials and Methods

Study framework and ethics approval

The project consisted of two components: a survey questionnaire (IRB#18205) and in-depth interviews (IRB#18395). Eligible participants had previously been invited to one of three COHCCC non-therapeutic breast cancer studies that collected blood and tissue samples only (IRB#15418, 17009, 17185). All work was approved by the COH Institutional Review Board, following institutional, state, and federal standards.

Summaries of the three breast cancer trials appear in **Table 1**. Participants were invited sequentially during clinic visits by CRA consenters, and demographic information is shown in **Table 2**.

Table 1. Overview of included clinical studies and data elements collected.

Protocol ID	Study Name & Aim	Face-to-Face Consent	Signed Consent Form	Materials & Information Gathered
15418	**Name:** Breast cancer initiation events in the high-risk population. **Aim:** Gather breast tissue and blood from persons with >20% elevated lifetime risk or with a breast cancer diagnosis.	Y	Y	Breast tissue, blood, DNA/RNA, demographic details, screening or cancer records (treatment, imaging, outcomes, genetic results, medical history).
17009	**Name:** Combined breast MRI/biomarker strategies to identify aggressive biology. **Aim:** Obtain 3 additional core biopsy samples from high-risk or diagnosed women undergoing MRI screening who need a core biopsy.	Y	Y	—
17185	**Name:** Breast microenvironment signaling during cancer initiation. **Aim:** Secure breast tissue and blood from individuals at >20% increased lifetime risk or diagnosed with breast cancer.	Y	Y	—

Table 2. Demographic characteristics of interview participants.

Demographic Characteristic	n (%)
Race	
Asian	8 (18%)
Black	8 (18%)
White	28 (63%)
Ethnicity	
Hispanic	21 (48%)
Non-Hispanic	23 (52%)
Age Group (years)	
25-35	8 (18%)
36-45	6 (14%)
46-55	14 (32%)
56-65	11 (25%)

66-75	5 (11%)
Breast Cancer Diagnosis in Past 5 Years	
Yes	41 (93%)
No	3 (7%)
Born in the United States	
Yes	25 (57%)
No	15 (34%)
Unknown	4 (9%)
Marital Status	
Single	15 (34%)
Married	26 (59%)
Divorced	3 (7%)
Religious Affiliation	
Yes	35 (80%)
No/Unknown	9 (20%)
Highest Education Level	
Graduate or professional school	7 (16%)
College degree	13 (29.5%)
Some college or associate's degree	8 (18%)
Vocational or technical school	4 (9%)
High school	7 (16%)
Some high school	2 (4.5%)
Unknown	3 (7%)

Survey questionnaire

Regardless of whether individuals had previously accepted or declined participation in any of the three non-interventional breast cancer trials, each was later contacted by another Clinical Research Assistant (CRA) who explained the details of this survey project (IRB#18205). The survey consisted of an anonymous, approximately 5-minute questionnaire designed to assess participants' perspectives on joining clinical trials. The instrument contained 39 items, evaluating:

(1) reasons for agreeing to or refusing the earlier study, and

(2) general perceptions toward medical and clinical research overall.

The objective was to explore how much the CRA consenter may have shaped the patient's decision either to enroll or to opt out, not only in the prior non-therapeutic trials but also in clinical research participation more broadly.

The questionnaire items were drawn from previous publications, focus group findings, and interview-based studies focused on attitudes toward the consent process. Before completing the survey, each participant reviewed and signed an information sheet approved by the COH Human Research Protections Office.

The first group of questions (Q1-Q9) asked respondents to rate their level of agreement with nine statements related to their most recent interaction with the CRA consenter. Responses were measured on a 7-point Likert scale ranging from "strongly disagree" to "strongly agree." These statements—adapted from Jenkins *et al*. 2009 and 2013 [8, 9], Overholser *et al*. 2007 [10], and Heiney *et al*. 2010 [11]—assessed perceptions of voluntariness, trust, empathy, emotional support, and empowerment during the consent discussion.

The second section (Q10-Q14) gathered information about participants' previous and current experiences with clinical research [12-14]. It included questions about whether respondents had taken part in the non-therapeutic BCT, prior invitations to research, and the influence of community or acquaintances who had engaged in similar studies.

Questions Q15-Q22 examined which characteristics of the consenter mattered most when a patient was invited to participate in a study. Respondents selected from "not important at all, " "somewhat important, " "important, " or "very important." This part, based on Myles, Heller, and Heiney [11, 15, 16], evaluated the significance of the consenter's race, language, gender, and demeanor.

The fourth block (Q23-Q34) explored motivators for participation in any type of clinical research, using the same four-point importance scale. Influencing factors included altruistic intent, religious beliefs, financial reward, and time commitment [17].

Finally, Q35-Q39 gathered demographic data such as race, ethnicity, spoken language, and education level.

Statistical analysis

Qualitative variables were summarized as frequencies and percentages. Associations were assessed using Chi-squared and Fisher's Exact tests. In analyses of the importance scale, responses marked "important" or "very important" were grouped together as important, whereas all remaining options were labeled not important. For items rated on the 7-point Likert scale, responses of "agree" and "strongly agree" were pooled under agree, and all others were classified as disagree.

In-person interviews

In a related qualitative study, CRAs and collaborating clinicians identified eligible participants during their routine outpatient appointments. The CRA invited each patient to join the interview study and obtained informed consent (IRB#18395). If the participant's schedule allowed, the interview was carried out on the same day in a private setting; otherwise, it was arranged for a later date coinciding with a follow-up visit at City of Hope.

Structured one-on-one interviews were conducted by trained CRAs **(Table 3)**. All CRA interviewers received instruction in effective communication, establishing rapport, and avoiding biased or leading questions, ensuring that discussions remained focused. Participants and interviewers were matched by gender and race to foster trust, cultural sensitivity, and open dialogue. No targeted recruitment by ethnicity or specialized diversity training was implemented.

The interview guide was designed to probe patient understanding of clinical research, motivations for participation, reasons for refusal, and perceived barriers or facilitators. For consistency, the same CRA who had obtained the participant's consent for IRB#18395 also conducted the interview session. With consent, all interviews were audio-recorded on digital devices to preserve accuracy. No monetary incentive was provided. Participants were reminded that they could decline or skip any question without penalty. After completion, CRAs documented field notes and reflections about each interview.

Table 3. Example Interview Questions.

Question #	Main Question	Follow-up Probes (if applicable)
1	Have you ever taken part in clinical research studies before?	**a.** Yes: Could you describe what the study focused on? **b.** No: What has kept you from participating?
2	In your view, what is clinical research?	**i.** Please explain in your own words what clinical research means to you. **ii.** What images or ideas come to mind when you hear "clinical research"?
3	How do you personally feel about clinical research?	Do you have any particularly strong emotions—positive or negative—about it?
4	Do you have any worries or concerns about joining a clinical research study?	**a.** Are there any risks that stand out to you? **b.** What obstacles might make it hard for you to take part?
5	Do you believe it is difficult for members of your community or cultural/ethnic group to participate in clinical research?	**a.** If yes, in what ways is it difficult? **b.** If no, why do you think it is not difficult?
6	From your perspective, what motivates people to join clinical research studies?	Among the reasons you listed, which ones do you consider most important?
7	Did anyone at City of Hope discuss clinical research participation with you?	**a.** Who were these individuals? **b.** What exactly did they say? **c.** Did their input affect your decision to join or decline?
8	A consenter is the staff member who explains the study and invites you to enroll. What qualities or traits do you think are essential for an effective consenter?	What specific actions should consenters take to help patients decide whether to participate?
9	What steps should institutions like City of Hope take to better educate patients about clinical research?	What additional measures could they implement to encourage greater patient involvement in research?

10	Is there any other information, opinion, or experience related to clinical research that we haven't covered and that you'd like us to know?	—

The audio recordings were transcribed verbatim and checked for precision. A three-member CRA team independently reviewed all transcripts to identify broad themes and subthemes. Each transcript was coded by two separate coders, who extracted representative quotes and reached consensus on thematic assignments. Once a minimum 95% inter-coder reliability was achieved, the finalized codebook with corresponding quotations was established. To preserve confidentiality, participant names were replaced with pseudonyms in all transcripts.

Results and Discussion

Survey questionnaire participation

Women eligible for IRB #18205 had earlier been invited to join one of three non-therapeutic, observational breast cancer studies **(Table 1)** designed to collect breast tissue, blood, and background data. Every woman approached for those trials qualified for inclusion in this follow-up survey assessing influences on research participation.

A total of 205 women were sequentially contacted as they presented to the Duarte Breast Oncology Clinic at City of Hope. Recruitment was consecutive with no attempt to favor or limit any racial or ethnic subgroup. Of these, 24 (11.7%) declined participation. The self-identified racial/ethnic composition among decliners was 13 Non-Hispanic White, 2 Asian, and 9 Hispanic/Latina.

The remaining 181 respondents completed the survey: 94 (52%) Northern European non-Hispanic White (NE White) and 87 (48%) Women of Color (WOC). Within the full cohort, 26% were Hispanic/Latina White, 17.1% Asian, 4.4% Black, and 1.7% Indigenous.

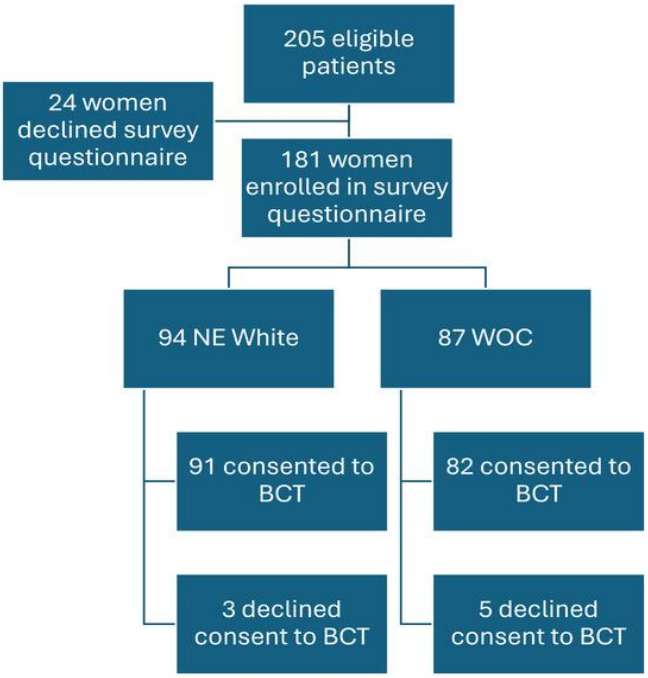

Figure 1. summarizes participant flow: among NE White respondents, 91 consented to the prior BCT while 3 declined; among WOC, 82 consented and 5 declined.

Participant demographics in these three background studies closely paralleled both (1) the racial distribution of patients in the City of Hope Duarte Clinic—52% Non-Hispanic White, 26% Latino/Latina, 8% Black, 14% Asian or Pacific Islander, <1% Indigenous—and (2) those within the broader City of Hope Comprehensive Cancer Center Catchment Area—57% Non-Hispanic White, 24% Latina, 11% Asian or Pacific Islander, 8% Black, <1% Indigenous.

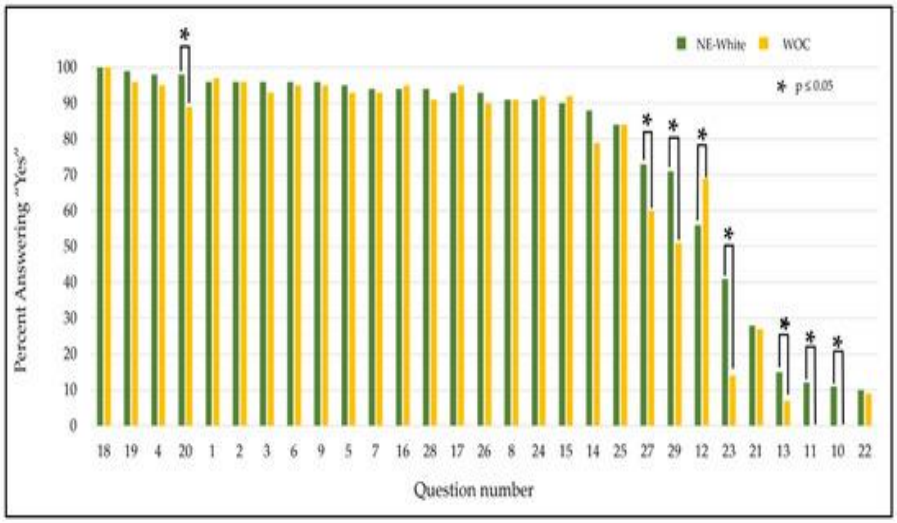

Figure 2. displays this distribution. In overall survey responses, WOC affirmed a higher proportion of "yes" answers than NE White participants, who exceeded WOC on only 1 of 29 items (*n = 181, *p ≤ 0.05).

Northern European non-Hispanic white participants (NE white)

Among the NE White cohort, 91 completed the written survey (91 enrolled; 3 declined). Summary findings appear in **Figure 2**. There were no statistical differences between enrollers and decliners regarding recognition that the study was voluntary (p = 1) or that they could withdraw freely (p = 1).

However, a significant distinction appeared in perceived trust and support generated by the consenter: 93% (n = 85) of those who enrolled felt supported versus 67% (n = 2) of those who declined (p = 0.05).

A second significant variance concerned feelings of empowerment—none of the decliners reported feeling empowered compared with 5% of enrollers (p = 0.02).

No other survey domains differed between enrolling and declining NE White participants.

Women of color (WOC)

Within the 87 WOC participants (82 enrolled; 5 declined), the group consisted of 26% Latina/Hispanic White, 17.1% Asian, 4.4% Black, and 1.7% Indigenous, with roughly half speaking a language other than English. Both enrollers and decliners acknowledged that joining the study was voluntary and that they were free to withdraw at any time.

Consistent with findings among NE White respondents, there was a notable gap regarding the sense of trust/support offered by the consenter: 94% (n = 77) of enrollers versus 60% (n = 3) of decliners agreed with that statement (p = 0.05).

Similarly, significant differences appeared in responses to feeling empowered to decide independently: 4% (n = 3) of enrollers and 40% (n = 2) of decliners disagreed that the consenter encouraged autonomy (p = 0.02).

Comparison between NE white and woc

Distinct contrasts were observed between NE White and WOC participants in their views about the consenter's characteristics and their influence on enrollment **(Figure 3)**. No NE White respondent (0%, n = 0) felt the race of the consenter affected their decision, whereas 11% (n = 9) of WOC participants did (p = 0.0009).

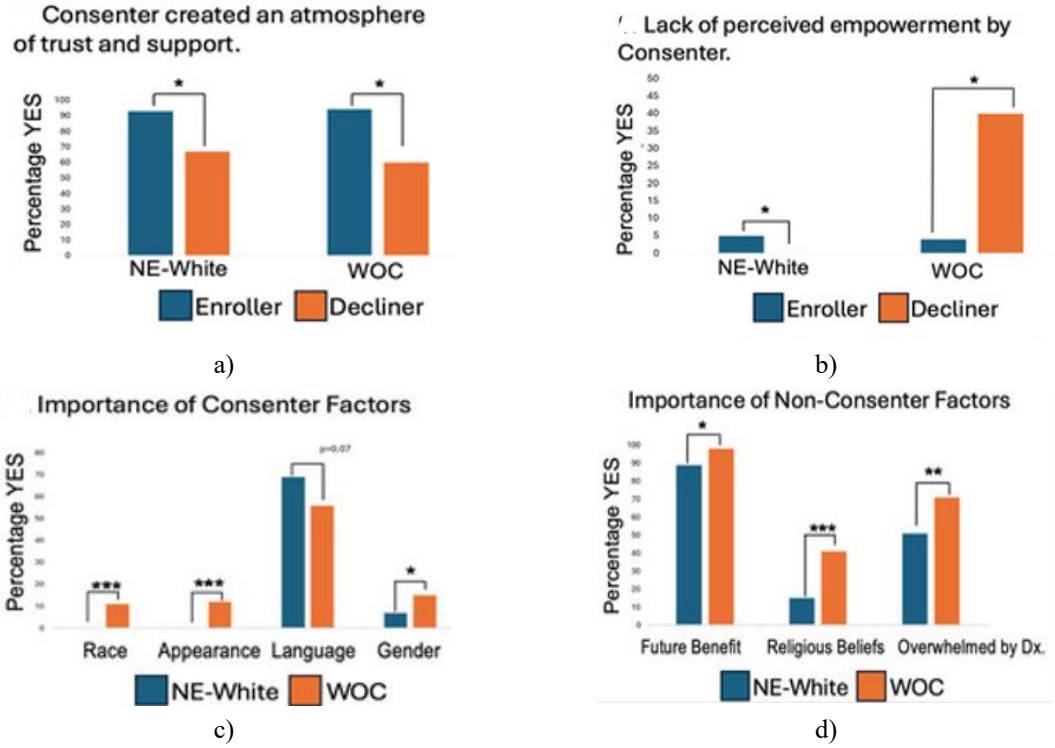

Figure 3. outlines group differences: (a) Comparison of perceived trust/support created by the consenter among NE White enrollers (n = 85) vs decliners (n = 2)** and WOC enrollers (n = 77) vs decliners (n = 3)** (p = 0.05). (b) Responses to not feeling empowered: NE White enrollers (n = 5) vs decliners (n = 0)** and WOC enrollers (n = 3) vs decliners (n = 2)** (p = 0.02). (c) Significance of consenter attributes: race (p = 0.0009), appearance (p = 0.0004), language (p = 0.07), gender (p = 0.08). (d) Significance of non-consenter factors: anticipated research benefit (p = 0.04), religious motivation (p = 0.0001), and feeling overwhelmed by diagnosis (p = 0.007).

None of the NE White respondents identified "looking like people from my community" as a relevant factor, whereas 12% (n = 10) of WOC participants considered it meaningful when deciding to take part in clinical research (p = 0.0004).

Although consent language and gender did not reach statistical significance between racial groups, they trended toward relevance. Consenter language was noted as important by 69% of NE White and 56% of WOC participants (p = 0.07), an unexpected observation likely reflecting the linguistic diversity within Los Angeles. The gender of the consenter was largely rated "not important, " with 93% of NE White and 85% of WOC enrollees selecting this response (p = 0.08). A follow-up breakdown showed that 68% of NE White and 51% of WOC regarded the consenter's language as a meaningful factor. The elevated proportion among NE Whites likely reflects the presence of immigrant subgroups from regions such as Eastern Europe, the Middle East, and Armenia.

Regarding non-consenter influences, significant group differences emerged. The perceived ability to help others in the future was considered important by 89% of NE White enrollees and 98% of WOC enrollees (p = 0.04). Religious beliefs were influential for 15% of NE White and 41% of WOC participants (p = 0.0001). Furthermore, feeling overwhelmed by a diagnosis or treatment affected 51% of NE White and 71% of WOC enrollees (p = 0.007). Across 8 of 24 survey items, statistically significant differences appeared between the two groups **(Figure 3)**. These items were concentrated within three major dimensions: (1) past or current research participation, (2) importance of consenter attributes, and (3) motivators for joining clinical studies.

Themes from in-person interviews

To gain deeper insight into women's perceptions, motivations, and reservations regarding clinical trials, in-person interviews were held to complement the earlier quantitative survey (IRB#18205). Between August 2019 and February 2020, 61 women were contacted who either (1) had previously consented to one of three observational studies (IRBs 15418, 17009, 17185), (2) were within five years of their breast cancer diagnosis, or (3) were at

elevated risk for the disease. Recruitment was sequential, following the order of patient clinic visits. Of those approached, 44 agreed to be interviewed.

The ethnic distribution among interviewees included 20 Latinas ([White/Hispanic]—1 Salvadoran, 1 Mexican-Armenian, 18 Mexican), 8 Asian (1 Chinese-Japanese, 1 Indian, 3 Chinese, 2 Vietnamese, 1 Thai), 8 African American/non-Hispanic, and 8 White/non-Hispanic (2 Iranian, 6 European). Participants ranged in age from 27 to 71 years. Seventeen women declined participation: 8 Asian, 4 Latina, 4 African American/non-Hispanic, and 1 White/non-Hispanic. Demographic details appear in **Table 2**, and interview prompts are listed in **Table 3**.

The interviews were conducted by three CRAs and one postdoctoral fellow, with interviewer-interviewee pairings matched by ethnicity: (1) Asian CRAs with Asian participants (East and West Asian), (2) a White Latina CRA with both Latina and Non-Hispanic participants, and (3) an African American postdoctoral fellow with African American participants. All sessions were held in English, lasting 4 to 49 minutes.

Key themes derived from transcripts included: scientific contribution, altruism, attitudes toward clinical research, incentives, research literacy, barriers and enablers, patient-centeredness, cultural responsiveness, and qualities of the consenter. These concepts emerged consistently across all ethnic backgrounds.

Positive themes

Participants frequently emphasized a desire to advance medical science and help others. For example, one African American woman expressed:

"If I knew my participation could help find better treatments—and that everyone could access them—it would be worth it." Similarly, an Asian participant noted: "Each research study serves a different purpose. Ultimately, it's about improving care, making treatments more effective, and hopefully discovering cures." The notion of scientific progress appeared as the most dominant positive driver across all groups.

Negative Themes: Distrust toward the medical system surfaced across all demographics, though it was more individualized among NE White women and more community-rooted among WOC. One NE White participant remarked:

"If you're given a placebo and no one knows what it is, there's risk in that. Even without a placebo, things can sometimes make you worse." For WOC, cultural mistrust emerged as a distinct subtheme. An Asian respondent shared: "I think a lot of Asian people struggle with trusting doctors. My relatives hesitate, especially with research—it feels experimental." An African American woman stated: "In my culture, we're taught that what happens at home stays at home." A Hispanic participant added: "In our culture, when they say 'clinical research, ' it sounds like being experimented on—like we're test subjects." African American participants also voiced the greatest concern about confidentiality.

Systemic Barriers and Facilitators: Across all racial/ethnic groups, barriers such as time, distance, and scheduling conflicts were frequently mentioned. One Asian participant commented:

"If the research visit could be on the same day as my appointment, that would help. It's hard to drive an hour just for the study." Other barriers included limited research literacy and language accessibility, the latter being most often cited by Asian participants. One remarked: "Sometimes patients can't consent because there's no form in their language. That's a real problem."

Consenter Qualities: All groups emphasized the importance of consent, professionalism, clarity, and emotional sensitivity. Participants noted that lengthy, legalistic consent forms and excessive signatures created barriers. Women expressed a preference for consenters who could explain studies thoroughly but succinctly, balancing professionalism with empathy.

Ensuring diverse representation in clinical trials is critical for the generalizability and safety of study findings and therapies across populations [18]. As a result, the National Cancer Institute (NCI) includes diversity in participant recruitment as one of the parameters used when accrediting cancer centers. Despite this emphasis, individuals identifying as Latina/Hispanic, Asian, or Black/African-American/African continue to be substantially underrepresented in both therapeutic and non-therapeutic clinical research [19-21].

In the present work, participants were enrolled in three trials focused on collecting demographic data, tissue, and blood samples. Our 90% participation rate aligns with those of similar biobanking or tissue-based studies but differs from many such efforts that have historically failed to include adequate numbers of Hispanic/Latino, Black/African American/African, Asian, and Indigenous populations [22, 23]. To illustrate, among the 5729 biospecimens in The Cancer Genome Atlas (TCGA) and the 2022 U.S. Census data, Non-Hispanic Whites were notably over-enrolled (58.9% vs. 77%; a 29% overrepresentation), while under-enrollment occurred among Black

(12.6% vs. 12%; −5%), Asian (6.1% vs. 3%; −51%), and Hispanic/Latino (19.1% vs. 3%; −84%) individuals [24]. Such disparities, especially in non-therapeutic databases like TCGA, limit the broader applicability of research conclusions.

Multiple factors contribute to the ongoing lack of diversity in both treatment-based and observational trials, making it a multifaceted challenge with no singular solution [25-30].

Unlike most previous reports, the composition of our participant cohort reflected the demographics of the City of Hope Duarte Clinic and its Comprehensive Cancer Center Catchment Area, avoiding both over- and under-representation of any racial or ethnic subgroup. No financial incentives were provided, and there were no directives emphasizing the recruitment of any particular community. Likewise, staff members responsible for obtaining informed consent received no specific diversity-related training. Given these neutral recruitment conditions, we hypothesized that the diversity among the consent administrators (CRAs) themselves may have positively influenced the inclusivity of trial participation.

Using a mixed-methods approach—combining quantitative survey data and qualitative interviews—this study examined the obstacles and facilitators impacting minority inclusion in research. Survey findings emphasized that, for Women of Color (WOC), shared racial or ethnic background with the individual obtaining consent significantly affected their willingness to participate. These results reinforce previously identified barriers. For example, Regnante *et al*. reported that achieving 10-50% minority enrollment required deliberate practices such as accurate race reporting, identifying participation barriers, developing targeted outreach strategies, and involving practitioners directly in trial promotion [31].

Distinct motivational and inhibiting factors emerged between non-Hispanic White (NE White) and WOC respondents. Qualitative interviews revealed a stronger sense of cultural mistrust among WOC participants—a theme absent among NE Whites—which also appeared in survey responses emphasizing the importance of cultural congruence with the consenter. Together, these findings suggest that mistrust in medical institutions remains a barrier and that diverse research staff can play a vital role in mitigating it. Moreover, given the heterogeneity within WOC populations, strategies to enhance participation must be community-specific, acknowledging each group's unique historical and social relationship with the healthcare system.

For WOC participants, altruism—the desire to help others—emerged as a stronger motivation compared to NE Whites. Similarly, religious beliefs had a greater influence on the decision to participate among WOC respondents. Religion often plays a central role in many minority communities, shaping their understanding of health, morality, life, and death, and consequently influencing their clinical trial decisions.

Additionally, WOC participants reported feeling more emotionally overwhelmed by their diagnoses and treatments, which may highlight their need for stronger emotional and psychosocial support throughout their medical journey. These insights underscore the importance of future research into the roles of faith, emotional resilience, and mental health support in improving trust, engagement, and retention of racial and ethnic minorities in clinical research.

Study limitations

Although this research captures participants' immediate reflections on their decision to either join or decline a clinical research study, several limitations restrict how broadly the findings can be applied. First, because our non-therapeutic trials already achieved high participation rates, opportunities to explore reasons for refusal were limited. Second, the sample sizes for both the survey and the interview components were relatively small, which may constrain statistical strength. Third, as the study was confined to non-therapeutic designs, factors relevant to therapeutic clinical trials were not evaluated. Fourth, the research design did not include a control group, which limits internal comparison.

An additional uncontrolled variable involved the age difference between those obtaining consent and the participants themselves. Since the consenters/interviewers were younger, this generational gap might have either positively or negatively influenced enrollment outcomes or responses. Future investigations will consider this potential confounding factor more explicitly.

Other notable limitations include the study's restriction to a single institution, its small cohort size, the exclusive inclusion of women, and its confinement to a specific geographic area—Los Angeles, California. Broader, multi-site studies are warranted to determine whether these results hold true across different populations and regions.

Conclusion

Despite the above constraints, the study offers evidence that characteristics of the clinical research team can meaningfully enhance diversity in clinical trial participation. The findings suggest that racial, ethnic, and socio-cultural alignment between participants and research staff may play a role in a patient's choice to engage in a study.

Further research involving larger, more diverse populations—including men and different age groups—is essential to substantiate these insights. In our non-therapeutic/non-interventional settings, participants were enrolled sequentially as they arrived at the clinic, reflecting the demographics of our catchment area without intentional over- or under-representation of any group.

Importantly, the research team did not receive specialized recruitment training or instructions to target specific racial or ethnic groups, ensuring equitable accrual.

Future work will aim to extend this investigation across multiple institutions and distinct community contexts, including those serving primarily Black/African-American women, to examine whether these findings persist in diverse clinical environments.

Ultimately, representative inclusion is essential for the validity, quality, and effectiveness of all healthcare research. In subsequent phases, we intend to assess whether diversity among consenters directly contributes to greater participant diversity in therapeutic multi-center clinical trials involving both men and women.

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Ethics Statement: None

References

1. Wendler D, Kington R, Madans J, Van Wye G, Christ-Schmidt H, Pratt LA, et al. Are racial and ethnic minorities less willing to participate in health research? PLoS Med. 2006;3(2):e19.
2. Wells JS, Pugh S, Boparai K, Rearden J, Yeager KA, Bruner DW. Cultural competency training to increase minority enrollment into radiation therapy clinical trials—an NRG Oncology RTOG study. J Cancer Educ. 2017;32(4):721–7.
3. Simon MS, Du W, Flaherty L, Philip PA, Lorusso P, Miree C, et al. Factors associated with breast cancer clinical trials participation and enrollment at a large academic medical center. J Clin Oncol. 2004;22(10):2046–52.
4. Wright JR, Crooks D, Ellis PM, Mings D, Whelan TJ. Factors that influence the recruitment of patients to Phase III studies in oncology. Cancer. 2002;95(7):1584–91.
5. Oyer RA, Hurley P, Boehmer L, Bruinooge SS, Levit K, Barrett N, et al. Increasing racial and ethnic diversity in cancer clinical trials: An American Society of Clinical Oncology and Association of Community Cancer Centers joint research statement. J Clin Oncol. 2022;40(20):2163–71.
6. Patel MI, Khateeb S, Coker T. Association of a lay health worker-led intervention on goals of care, quality of life, and clinical trial participation among low-income and minority adults with cancer. JCO Oncol Pract. 2021;17(4):e1753–62.
7. Kelsey MD, Patrick-Lake B, Abdulai R, Broedl UC, Brown A, Cohn E, et al. Inclusion and diversity in clinical trials: Actionable steps to drive lasting change. Contemp Clin Trials. 2022;116:106740.
8. Jenkins V, Farewell V, Farewell D, Darmanin J, Wagstaff J, Langridge C, Fallowfield L. Drivers and barriers to patient participation in RCTs. Br J Cancer. 2013;108(7):1402–7.
9. Jenkins V, Fallowfield L, Solis-Trapala I, Langridge C, Farewell V. Discussing randomised clinical trials of cancer therapy: Evaluation of a Cancer Research UK training programme. BMJ. 2005;330(7485):400.
10. Overholser J. The central role of the therapeutic alliance: A simulated interview with Carl Rogers. J Contemp Psychother. 2007;37(2):71–8.

11. Heiney SP, Adams SA, Wells LM, Johnson H. Evaluation of conceptual framework for recruitment of African American patients with breast cancer. Oncol Nurs Forum. 2010;37(4):E160–7.
12. Kurt A, Semler L, Jacoby JL, Johnson MB, Careyva BA, Stello B, et al. Racial differences among factors associated with participation in clinical research trials. J Racial Ethn Health Disparities. 2016;4(5):827–36.
13. Locock L, Smith L. Personal benefit, or benefiting others? Deciding whether to take part in clinical trials. Clin Trials. 2011;8(1):85–93.
14. Bulmer M. Neighbours: The Work of Philip Abrams. Cambridge: Cambridge University Press; 1986.
15. Myles S, Tocci C, Falk M, Lynch S, Torres C, Brown B, et al. A multicenter investigation of factors influencing women's participation in clinical trials. J Womens Health. 2018;27(2):258–70.
16. Heller C, Balls-Berry JE, Nery JD, Erwin PJ, Littleton D, Kim M, Kuo WP. Strategies addressing barriers to clinical trial enrollment of underrepresented populations: A systematic review. Contemp Clin Trials. 2014;39(2):169–82.
17. Cortés YI, Arcia A, Kearney J, Luchsinger J, Lucero RJ. Urban-dwelling community members' views on biomedical research engagement. Qual Health Res. 2017;27(1):130–7.
18. Hamel LM, Penner LA, Albrecht TL, Heath E, Gwede CK, Eggly S. Barriers to clinical trial enrollment in racial and ethnic minority patients with cancer. Cancer Control. 2016;23(4):327–37.
19. Loree JM, Anand S, Dasari A, Unger JM, Gothwal A, Ellis LM, et al. Disparity of race reporting and representation in clinical trials leading to cancer drug approvals from 2008 to 2018. JAMA Oncol. 2019;5(10):e191870.
20. Ford ME, Siminoff LA, Pickelsimer E, Mainous AG, Smith DW, Diaz VA, et al. Unequal burden of disease, unequal participation in clinical trials: Solutions from African American and Latino community members. Health Soc Work. 2013;38(1):29–38.
21. Gorelick PB, Harris Y, Burnett B, Bonecutter FJ. The recruitment triangle: Reasons why African Americans enroll, refuse to enroll, or voluntarily withdraw from a clinical trial. An interim report from the African-American Antiplatelet Stroke Prevention Study (AAASPS). J Natl Med Assoc. 1998;90(3):141–5.
22. Baer AR, Smith ML, Bendell JC. Donating tissue for research: Patient and provider perspectives. J Oncol Pract. 2011;7(5):334–7.
23. Frank ES, Burns RT, Carbine NE, Cargen L, Chauhan C, Cline DK, et al. Collecting tissue for research purposes: A survey of 16 institutions in the Translational Breast Cancer Research Consortium (TBCRC). J Clin Oncol. 2011;29(36):10615.
24. Spratt DE, Chan T, Waldron L, Speers C, Feng FY, Ogunwobi OO, Osborne JR. Racial/ethnic disparities in genomic sequencing. JAMA Oncol. 2016;2(8):1070–4.
25. Penberthy L, Brown R, Wilson-Genderson M, Dahman B, Ginder G, Siminoff LA. Barriers to therapeutic clinical trials enrollment: Differences between African-American and white cancer patients identified at the time of eligibility assessment. Clin Trials. 2012;9(6):788–97.
26. Rivers D, August EM, Sehovic I, Lee Green B, Quinn GP. A systematic review of the factors influencing African Americans' participation in cancer clinical trials. Contemp Clin Trials. 2013;35(1):13–32.
27. Burlew K, Larios S, Suarez-Morales L, Holmes B, Venner K, Chavez R. Increasing ethnic minority participation in substance abuse clinical trials: Lessons learned in the National Institute on Drug Abuse's Clinical Trials Network. Cult Divers Ethn Minor Psychol. 2011;17(3):345–56.
28. Fisher-Hoch SP, Below JE, North KE, McCormick JB. Challenges and strategies for recruitment of minorities to clinical research and trials. J Clin Transl Sci. 2023;7(1):e154.
29. Heffernan ME, Barrera L, Guzman ZR, Golbeck E, Jedraszko AM, Hays PT, et al. Barriers and facilitators to recruitment of underrepresented research participants: Perspectives of clinical research coordinators. J Clin Transl Sci. 2023;7(1):e193.
30. Clark LT, Watkins L, Piña IL, Elmer M, Akinboboye O, Gorham M, et al. Increasing diversity in clinical trials: Overcoming critical barriers. Curr Probl Cardiol. 2019;44(4):148–72.
31. Regnante JM, Richie N, Fashoyin-Aje L, Hall LL, Highsmith Q, Louis JA, et al. Operational strategies in US cancer centers of excellence that support the successful accrual of racial and ethnic minorities in clinical trials. Contemp Clin Trials Commun. 2020;17:100532.