Journal of Community Medicine & Public Health
Hilliard AL, et al. J Community Med Public Health 10: 564
www.doi.org/10.29011/2577-2228.100564
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Research Article

# Local Leaders' View on Racial and Ethnic Minority Clinical Trials Enrollment

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**Citation:** Hilliard AL, Thompson SL, Javanmardi CA, Larose-Pierre M, Darling-Reed S, et al. (2026) Local Leaders' View on Racial and Ethnic Minority Clinical Trials Enrollment. J Community Med Public Health 10: 564. DOI: https://doi.org/10.29011/2577-2228.100564

**Received Date:** 28 March, 2026; **Accepted Date:** 06 April, 2026; **Published Date:** 10 April, 2026

## Abstract

**Purpose:** Racial and ethnic populations have been underrepresented in clinical trials. This study evaluated community leaders' knowledge, beliefs, and attitudes toward the participation of racial and ethnic minority populations in COVID-19 clinical trials. **Design Methods:** Virtual focus groups with questions aimed at increasing clinical trial participation were conducted via Zoom in three cities in Florida—Tallahassee, Jacksonville, and Tampa. Each group included 5-8 participants, all of whom were racial and ethnic minority community leaders from social, academic, and religious organizations. Data from the focus groups were transcribed verbatim using several transcribers. The transcripts were organized, coded, and analyzed utilizing NVivo qualitative software. A general code list was developed based on a review of the transcripts. Multiple reviewers further refined the code list of themes to allow for inter-coder reliability checks. **Results / Expected Results:** Nineteen participants from Tallahassee, Jacksonville, and Tampa participated in the three focus groups. These respondents included 42% between the ages of 45-54, 58% female, and 95% Black or African American. Data analysis using NVivo 14 software revealed common themes, including concerns about clinical trials, distrust, and a general lack of knowledge and awareness about clinical trials. Fostering partnerships between Historically Black Colleges and Universities (HBCUs) and community leaders was identified as a promising strategy. **Discussion / Conclusion:** Racial and ethnic community leaders felt more comfortable participating in clinical trials led by an HBCU. They all agreed that relationships with the community and the credibility of HBCU faculty would enhance their willingness to participate in clinical trials.

**Keywords:** Racial and ethnic minorities; Clinical trials; COVID-19; Community leaders

**SDG Keywords:** Good health and well-being; Quality education; Reduced inequalities; Partnerships for the goals

## Introduction

Health disparities continue to impact racial and ethnic minority populations in the United States [1-3]. These populations are also disproportionately exposed to many environmental toxins that have been shown to increase the risk and incidence of an array of illnesses and diseases [4-7]. The beginning of 2020 brought yet another disease that impacted the health of racial and ethnic minority populations: coronavirus disease 2019 (COVID-19). By the end of 2020, underrepresented racial and ethnic populations, particularly Black or African American and Hispanic or Latino communities, experienced disproportionately higher death rates from COVID-19 compared to other demographic groups [8].

The end of 2020 also brought about the first distribution of COVID-19 vaccines. Efforts to curb the impact of COVID-19 have been hindered by vaccination challenges within communities

most affected by COVID-19. For instance, in Mississippi, Black or African Americans constitute only 15% of vaccinations but represent 38% of COVID-19 cases and 42% of related deaths [9]. Similar trends are observed in Delaware, where Black or African Americans represent 8% of vaccinations but comprise nearly 25% of COVID-19-related deaths [9]. The elevated morbidity and mortality rates among Black or African Americans further demonstrate health disparities [10-12]. Addressing the reluctance of Black or African Americans to participate in vaccination efforts and clinical trials is crucial to narrowing this gap in health outcomes [13].

Recent studies have identified three common themes around perceptions of vaccinations in racial and ethnic minority communities: vaccine accessibility, vaccine hesitancy, and vaccine resistance. Vaccine accessibility encompasses challenges individuals face in utilizing healthcare services, including transportation barriers, work-related issues, and limited internet access to relevant information, especially among elderly Black or African Americans [14]. Vaccine hesitancy, characterized by delayed acceptance or refusal of a vaccine, is particularly pronounced among lower socioeconomic demographics, with trust in vaccines playing a pivotal role in shaping perceptions [8, 14]. Finally, vaccine resistance, rooted in historical and contemporary distrust of the US medical system, poses a significant barrier to widespread vaccination acceptance, requiring targeted efforts to rebuild trust in racial and ethnic minority communities [14].

Recent studies have also indicated that reluctance among racial and ethnic minority populations extends beyond vaccinations to include participation in clinical trials. Issues such as historical events, exemplified by the Tuskegee syphilis experiment [15], contribute to mistrust in the healthcare system. This mistrust is deepened by implicit biases in modern healthcare environments, where assumptions about patient behaviors, lack of interest, and poor communication during clinical trial recruitment are prevalent [16, 17]. Examples include longer wait times and less time spent with patients of color compared to White patients, as well as subtle biases like dominant or dismissive communication styles, and unequal diagnostic thoroughness or treatment recommendations [18]. False beliefs about biological differences, rooted in historical racism, persist in modern medical practice, leading to disparities such as the undertreatment of pain in Black patients [19]. Research has shown that some medical students and residents endorse these false beliefs, which contribute to biased pain assessments and inaccurate treatment recommendations for Black patients [19, 20]. These biases create barriers to participation for minority groups and perpetuate their skepticism toward clinical research [16, 17].

It is incumbent upon medical professionals and researchers to build trust within racial and ethnic communities, recognizing the historical context, and addressing contemporary concerns. This trust-building effort is essential for fostering increased participation in both vaccinations and clinical trials [21], ensuring that racial and ethnic communities are aware of and have equitable access to advancements in healthcare.

We sought to address these challenges through community-based participatory research (CBPR), a proven approach for engaging communities disproportionately affected by racial/ethnic disparities [22]. Through a comprehensive and community-focused approach, our study aimed to address the pandemic's immediate challenges, foster trust, and promote long-term health equity within racial and ethnic communities. By fostering collaborative and equitable partnerships with local racial and ethnic minority community organizations and utilizing established toolkits from the Center for Disease Control and Prevention (CDC) [23], we hope to develop targeted strategies to actively improve the enrollment of racial and ethnic communities in local COVID-19 vaccinations and clinical trials.

## Materials and Methods

We used multiple approaches to recruit participants for three community leaders' focus groups. Focus groups were conducted from December 2022 through January 2023 [24]. Each focus group had 5-8 participants. Recruitment methods included social media outlets, flyer distribution, academic departments, organizations, satellite campuses, and community outreach efforts. The focus groups aimed to discuss strategies for increasing racial and ethnic minority participation in COVID-19 clinical trials. Sessions were conducted in Tallahassee, Jacksonville, and Tampa, Florida, lasting approximately 60 minutes each via the Zoom platform. Participants received a $50 gift card as an incentive for their involvement. This study received approval from the Florida A&M University Institutional Review Board (IRB # 1944260-3). To ensure coding reliability in the analysis of focus group data, several steps were taken to emphasize inter-coder reliability checks. Data were transcribed verbatim by multiple transcribers to maintain the accuracy of participant responses. The transcripts were organized and coded using NVivo qualitative software (©QSR International Pty Ltd. 2012), which facilitated the systematic management of our data sets.

The coding process began with one reviewer identifying key themes based on the a priori objectives outlined in the focus group guide. A general code list (Table 2) was created as a result of this preliminary review, ensuring that the initial analysis was structured around the study's objectives. The code list was refined after the first coding pass to ensure coding reliability further. Multiple reviewers were involved in the process, allowing inter-coder reliability checks.

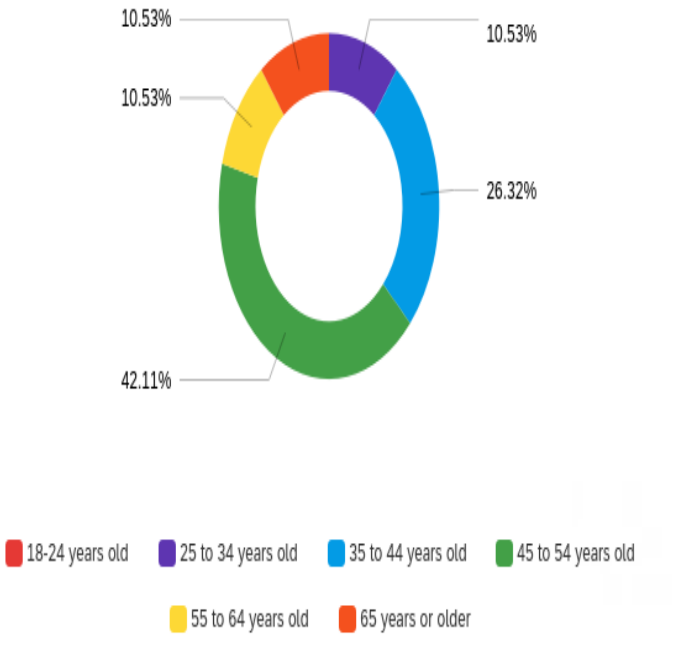
Reviewers independently applied the refined code list to sections of the transcripts and then met to discuss their coding decisions. Discrepancies in coding were addressed through discussion to ensure that all reviewers had a shared understanding of the themes. This process helped ensure consistency in how codes were applied across the transcripts. The iterative refinement of the code list and the regular inter-coder discussions minimized subjectivity and improved the trustworthiness of the findings.

## Results

A series of focus groups were conducted, representing 19 community leaders. These sessions were conducted across three Florida Counties: Duval County in Jacksonville, Leon County in Tallahassee, and Hillsboro County in Tampa. The primary aim of these focus groups was to gather insights from community leaders regarding the purpose, historical context, and barriers associated with minority participation in COVID-19 vaccination clinical trials.

### Age and Gender Demographics

The age demographics of the focus groups are shown in Figure 1. The data reveals a diverse distribution across age groups, with the majority falling within the 45 to 54 years old category, comprising 42.11% of the participants (Figure 1A). Individuals aged 35 to 44 represented the second-largest group, constituting 26.32% of the population (Figure 1A). Each of the 25 to 34 years old, 55 to 64 years old, and 65 years or older groups comprised 10.53% of participants (Figure 1A). No individuals from the 18-24 age group participated in the focus groups. Among the participants, 57.89% identified as female, while 42.11% identified as male (Figure 1B).




A.

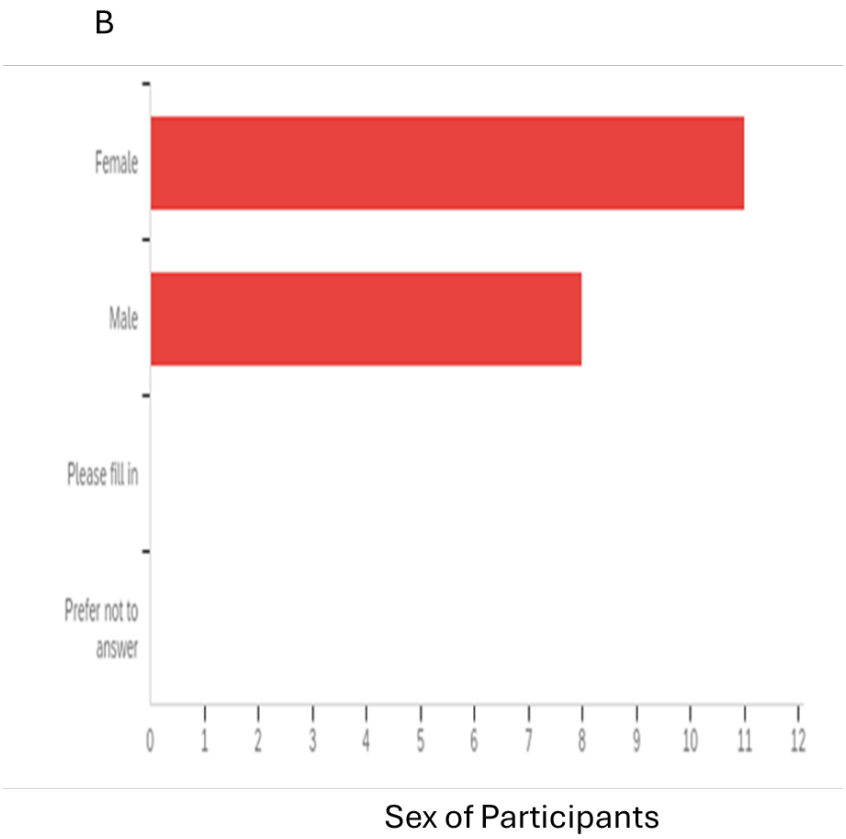
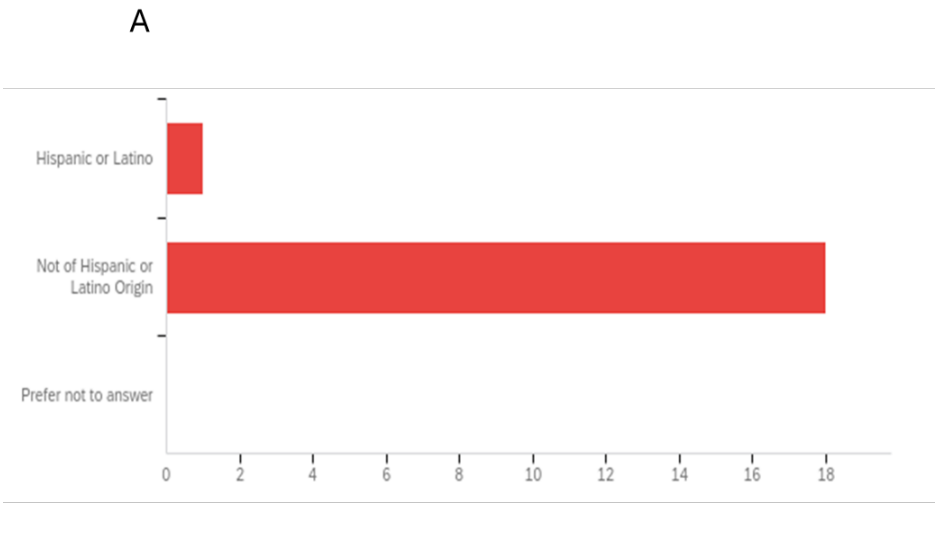
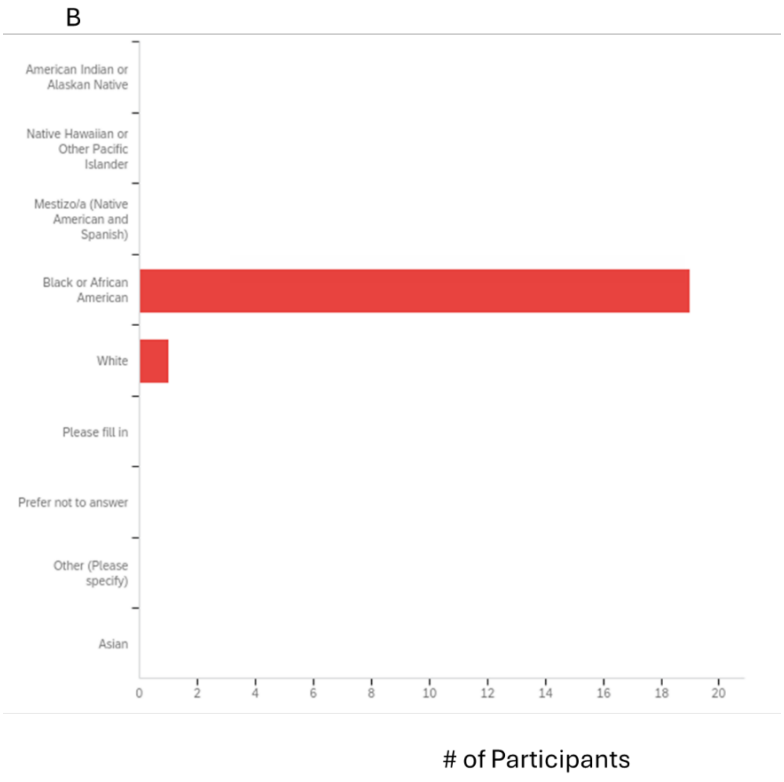



**Figure 1:** Age (A) and gender demographics (B) of the focus groups.

**Racial and Ethnic Demographics**

Most participants (94.74%, n = 18) were identified as not of Hispanic or Latino origin, whereas a single participant (5.26%, n = 1) identified as Hispanic or Latino (Figure 2A). Participants were allowed to select multiple options when asked about their racial background. The highest proportion (94.74%, n = 18) was identified as Black or African American (Figure 2B). A smaller percentage (5.26%, n = 1) reported their race as White (Figure 2B). None of the participants selected other racial categories, preferred not to answer, or specified their racial background. Regarding language preferences at home, a significant majority (93.33%) reported speaking "English" (Figure 2C). None of the participants indicated "Spanish" as their primary language (Figure 2C). A single participant (6.67%) reported speaking "Other" languages at home (Figure 2C).


A
Hispanic or Latino
Not of Hispanic or Latino Origin
Prefer not to answer
0
2
4
6
8
10
12
14
16
18
# of participants


B
American Indian or Alaskan Native
Native Hawaiian or Other Pacific Islander
Mestizo/a (Native American and Spanish)
Black or African American
White
Please fill in
Prefer not to answer
Other (Please specify)
Asian
0
2
4
6
8
10
12
14
16
18
20
# of Participants

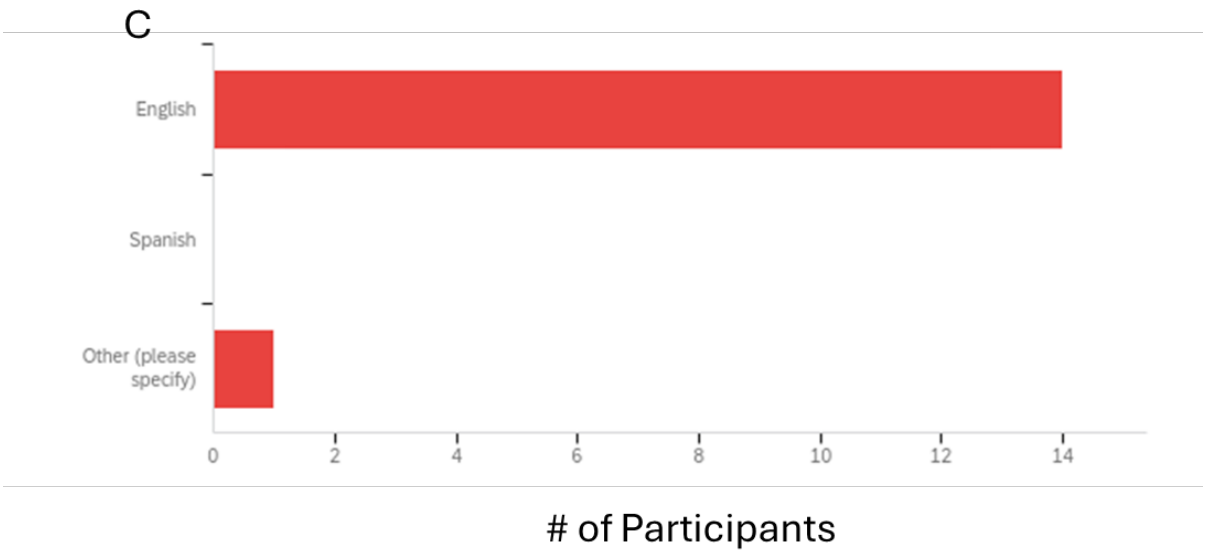
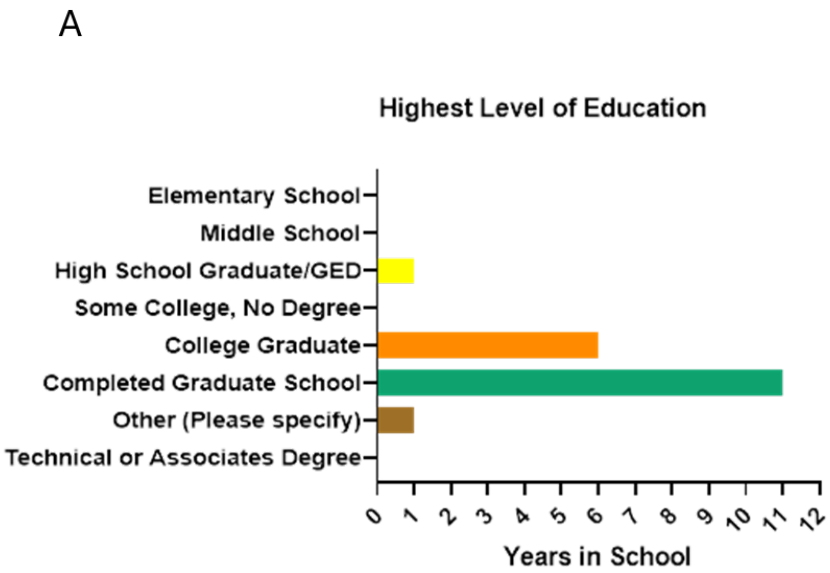



**Figure 2: Racial and ethnic demographics represented in the study groups.** (A) Hispanic or Latino origin (B) Racial demographic (C) Primary language.

**Socioeconomic Demographics**

The educational background of the participants in the study indicates a diverse range, with a sizable portion having completed graduate school (57.89%) and a notable percentage having attained a college graduate degree (31.58%) (Figure 3A). In terms of residential distribution, 42.11% (n=8) reside in Jacksonville, (31.58%) (n=6) reside in Tampa and (26.32%) (n=5) reside in Tallahassee (Figure 3B). The majority (89.47%) reported being employed full-time, (Figure 3C).



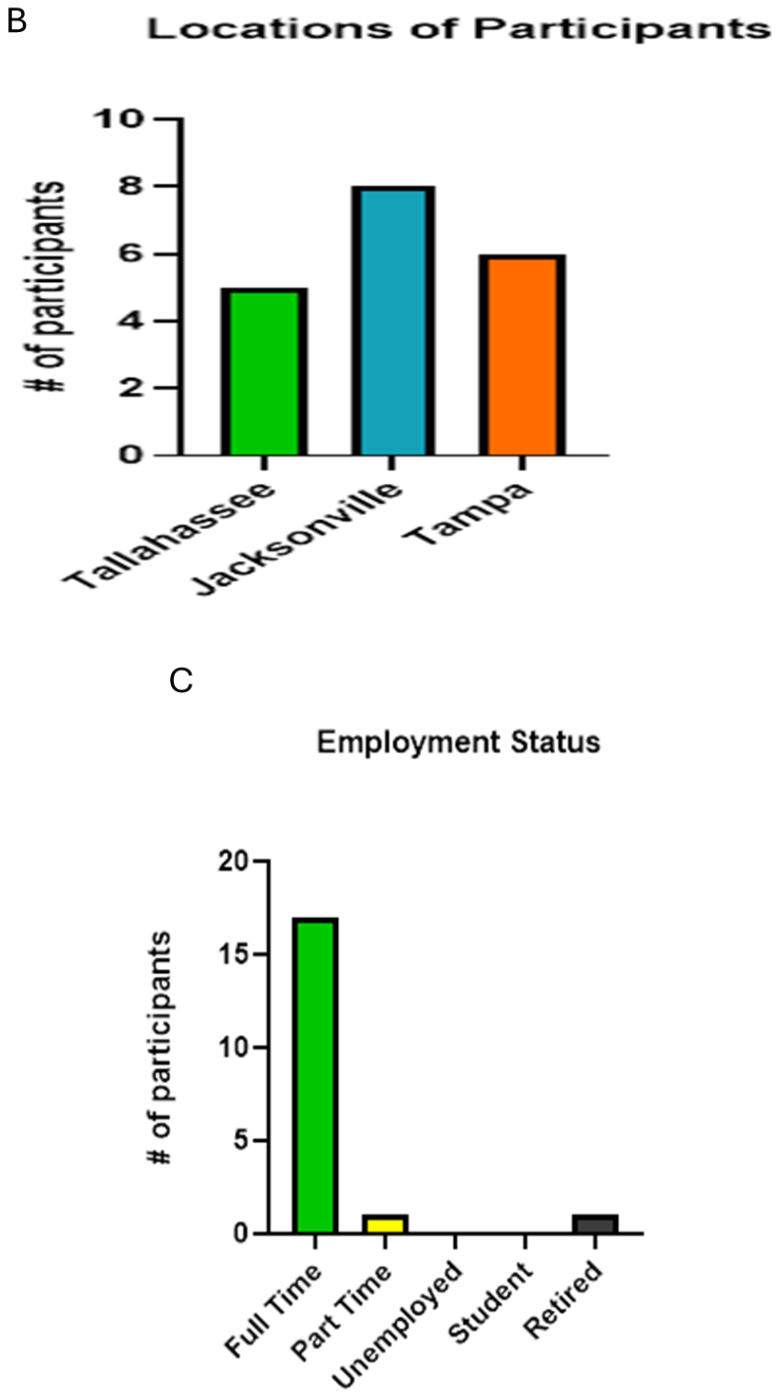



**Figure 3: Socioeconomic demographics.** (A) Education level (B) Residential distribution (C) Employment status.

The data on community leadership roles within the focus group highlights various positions and affiliations among the participants, namely the Black or African American participants (Table 1). This varied group of community leaders reflects a broad cross-section of expertise, influence, and involvement in different sectors. Their diverse backgrounds, from education and healthcare to social services and non-profit work, offer a comprehensive understanding of the challenges and opportunities in engaging racial and ethnic communities in clinical research.

| |
|---|
| Advocate for Seniors |
| Community Development |
| Alpha Kappa Alpha Sorority |
| Pastor and Staff Pharmacist |
| Advisor |
| Social Services - Domestic violence & homeless population |
| Not for profit. |
| Nonprofit |
| Bishop |
| School Counselor |
| High School Principal |
| Pastor |
| Social and Human Services Leader & Children & Family |
| City Commissioner |

**Table 1:** Types of community leaders in focus groups.

**Focus Group Participant Feedback Analyses**

Based on the initial review and analysis of the transcripts, a preliminary code list (Table 2) was generated. The reviewers further refined this code list through additional coding passes.

| Name | Description | Files | References |
|---|---|---|---|
| Barriers | What are any barriers that would impede someone to join a clinical trial, trust clinical trials, travel to the trial, or encourage anyone to participate? | 6 | 136 |
| Benefits of Clinical Trials | What benefits could be received from clinical trial participation, rather it be COVID-19 related or not? | 6 | 19 |
| Clinical Trial Awareness Advocacy | Are you aware of any entity that is encouraging advocating for clinical trial awareness? Do you know any community outreach engagements for them? | 5 | 63 |
| Clinical Trial Consent Knowledge | What do you know about any information regarding clinical trial consent for participants? | 4 | 8 |
| Clinical Trial Experience | Have you or anyone you know participated in a clinical trial? Would you participate in a clinical trial? | 7 | 57 |
| Clinical Trial Recommendations to Community | How would you encourage your community to participate in clinical trials? | 3 | 5 |
| Clinical Trial Compensation | What should the compensation be for participation in clinical trials? | 6 | 24 |

| | | | |
|---|---|---|---|
| COVID 19 Clinical Trial Participation | Have you ever participated in a COVID-19 Clinical Trial? Do you know anyone who has? Would you participate? | 7 | 97 |
| COVID Clinical Trial Information | What advertisements, information, or awareness have you seen for COVID-19 Clinical Trial access? | 7 | 73 |
| COVID-19 Vaccines | What do you know about the COVID-19 Vaccine Clinical Trials | 6 | 26 |
| DEI | What are some opportunities or advantages/disadvantages involving lack of diversity, equity, and inclusion with healthcare or in clinical trials? Does this contribute to racial and ethnic disparities? | 7 | 64 |
| General Knowledge of Clinical Trials | When you think of clinical trials, what comes to mind? | 7 | 45 |
| HBCUs | Are you aware of any clinical trial information or trust information stemming from HBCUs? | 4 | 8 |
| Religious and Cultural Beliefs | How does religion or culture impede or aid in clinical trial participation? | 5 | 18 |
| Trust in Healthcare | What are some reasons why you do not have trust in the healthcare system? | 6 | 30 |

**Table 2:** List of code descriptions.

**General Knowledge of Clinical Trials**

We explored participants' perceptions and experiences regarding clinical trials. Participants were asked to describe their level of knowledge about clinical trials. Most community leaders said it was a science experiment or a research project. One community leader emphasized the role of clinical trials in tailoring treatments to demographics and stated:

*"Clinical trials are more of the practice component of medicine, where you're trying to figure out what's going to be the best suited for demographic, age group, ethnicity, and geographical location. And so that's pretty much the difference between the two."*

Another community leader explained,

*"Yes, when I hear clinical trials, I think of experimental drugs."*

One healthcare provider group generally had a more nuanced understanding, seeing clinical trials as opportunities for treatment access. A participant in this group stated:

*"Well, I was thinking opportunity. There is an opportunity to receive treatment, or possible cure or treatment for something that could without health insurance, could seem unaffordable, or even with health insurance, sometimes can present an opportunity for something to be affordable."*

A small number of participants had previously participated in a clinical trial. One community leader regarded his experience and how the experience impacted him:

*"Well there was not very much to it, I mean I don't know if you know if you're looking for whether the pleasurable experience if it just wasn't a whole lot to it on my end in my participation and I participated specifically because of the fact that you don't get a lot of people of color to participate in this process so that was my sole motivation to participate because of that."*

A few participants or their family members had participated in a clinical trial. The trials mentioned were ADHD and multiple myeloma. As these participants stated:

*"I actually participated in a clinical trial for multiple myeloma. It lasted, I believe, about 18 months."*

*"I have been invited to get involved in several others since the completion of the one that I did before. But they were not things that necessarily interested me, so I passed on those."*

Another set of healthcare provider had first-hand clinical trial experience as both participants and investigators, one citing a successful trial for glaucoma treatment:

*"I participated in a clinical trial for eye drops for glaucoma treatment. I visited the physician's office once a week for 6 months to pick up the eyedrops. I documented any side effects on a tablet. The drug went on to be FDA approved".*

### Clinical Trial Information Access

Participants in both the healthcare provider and community leader groups expressed diverse perspectives on the availability of information and access to clinical trials, particularly in the context of COVID-19 trials. Some community leaders noted a need for more data supporting the influence of celebrity endorsements on increased vaccination rates among people of color. A community leader stated,

*"I don't know that there is any data out there I would say during COVID a lot of the celebrities who were vaccinated and who were pushing for vaccines were advertising and pushing for it but I don't like you said I don't know that there's any data that supports the fact that more people of color got vaccinated because of that."*

Others highlighted the general public's uncertainty about clinical trials, citing commercials and social media as sources of information, stating:

*"I think a lot of people see the commercials or on TV or social media and they're not sure what clinical trials are and how they can participate, and how that benefits people generally, but certainly people of color."*

Within the healthcare provider group, opinions varied. Some rely on their alma maters for information, while others consider themselves "unicorns" who independently seek and discern information. One participant stated the following:

*"I will bet you to say that say that those of us who are on the phone are probably unicorns and as much that we are our own information source. I would venture to say that the people on this call are readers and they have capacity to design truth from fiction. But that's not the vast majority of people. We still hold our past regards in high regards as sources of information. We still hold our community folk depending on the work that you do as sources of information. you know we are not a monolith in terms of where our information comes from and how we receive it and discern it but for me you know I'm a reader and I'm also engaged at really high levels around stuff like this so I'm my own source for the most part for information but again I would venture to say everybody on this call is but we are not the norm. Our people still get their information from line and milk."*

Another participant, however, stated that in their community, they received consistent outreach about clinical trial information from advertisements, billboards, and other sources (Table 3). A community leader stated:

*"There were several universities in Louisiana that did significant outreach in recruiting different race, sex and age range for clinical trials. They used billboards and advertisements in the churches and things like that to talk about their clinical trials."*

| |
|---|
| Clinics |
| Internet |
| Colleges |
| Their primary care provider |
| Social media |
| Celebrities* |
| Commercials on both TV and radio |
| Their pharmacist |
| Articles |

**Table 3:** Sources from which participants obtained information about clinical trials.

### Willingness to Participate

All participants were assessed on their willingness to participate in a clinical trial in general and related explicitly to COVID-19 and their willingness to encourage their patients, family members, or fellow community members to participate. Although many participants stated that their hesitancy was more pronounced than their willingness to participate, others indicated that they needed clarification due to the uncertainty of the results. Some of these remarks included:

*"Even though I'm vaccinated [I would say I'm a little hesitant based off of just all the research and information that was put out that wasn't really clear so I would definitely need more clarity on participating in a trial that was COVID-19 related]."*

*"It would depend on the type of clinical trial. I would be hesitant due to health issues with my lung."*

*"Overall I don't think so. The reason would be due to the variation in strains. It's almost seeming as though you got to keep the vaccination. It's gonna almost become like the flu. How would the trial be beneficial if the strain changes each year?"*

*"I have personally do not trust the clinical trials process, just because, as someone mentioned before, of history, especially with black and brown people in this country. We have participated in things that have resulted in death or like illness, and nothing was really done about it, and so I would probably not participate. If something happens to me, then I just don't feel like anyone would really care about that. They would go on to the next person to try to get them to participate as well."*

Despite the hesitancy, some participants identified factors that could increase their willingness to participate, such as a preference for participating in clinical trials related to diseases they are passionate about. A community leader suggested,

*"Think if they are able to engage community leaders more to gain*

*trust within the community. Minority communities would feel more comfortable overall. Monetary gifts are important, but I think you run the risk of leaning towards the same populations and bias. If they engage with community leaders more to build that long-standing trust that can be helpful". Another participant stated that they don't necessarily agree with participating in a COVID-19 clinical trial but perhaps another disease state that they are passionate about. The participant remarked, "I'm not the biggest advocate for COVID, I would say no. But if it was something that was closer to home, and I cared about such as Alzheimer's dementia or cancer related. I would be more apt."*

**Barriers to Clinical Trial Participation**

The focus groups were assessed on trust and barriers to clinical trial involvement. Participants highlighted racism, lack of diversity, and historical events like the Tuskegee experiment as key factors or a lack of trust in not only clinical trial participation but also the healthcare system. Participants expressed feeling ignored or not prioritized in clinical settings, citing historical mistrust and current disparities in healthcare. Access to trial information was also deemed inadequate, with socioeconomic barriers further limiting their ability to participation. Two participants stated:

*"Yes, I think you know, a participant mentioned this several times about the Tuskegee experiment and people, of course, our generation, I'm of that generation. That's very familiar with the Tuskegee experiment, you know, for a lot of us that had a very profound effect on, I think the African American Communities' Trust of the medical Community, because we were literally experimented on in that respect, and so that I think that colored our view of the medical profession, and its practices for years."*

*"I think the fear in the African American community of our past in this country with being subjects of clinical trials unknowingly just, not having favorable outcomes, having disastrous outcomes that affected us or impacted our race in a horrible way. So, and it's not that long ago we're not talking over a 100 years ago. We're talking about within the last, I don't know 40, 50 years."*

A pharmacy student underscored the perception of racial and ethnic communities not feeling prioritized in clinical settings by stating:

*"I feel like a lot of minorities don't feel prioritized in clinical settings."*

Another learner alluded to participant referenced historical mistrust of Black or African Americans in healthcare. She stated:

*"Well, I think it's just about history, honestly, especially for African Americans. And you know how we were treated back then. So, . I hear a lot about pregnant women and the doctors' offices, and they would be totally ignored about their symptoms. They will be told that they're over exaggerating and that they're really not feeling what they're feeling."*

Lack of access to information about clinical trial opportunities was identified as a barrier, with a participant expressing dissatisfaction with researchers' efforts in ensuring participants' comfort. These comments included:

*"[I think those should be a lead in relative to making people feel at least having a level of ease around the decision that they're making to participate but I don't think researchers have done a really good job of letting people know.] I think that's more of an internal thing relative to IRB etcetera and so you know it's been my experience that researchers are there to get participants and that's it and down any other level of comfort that they could or would or should even provide to the participant hasn't been there thus I think you get a lack of people really interested in trials."*

Additional barriers included the impact of lower socioeconomic status on access to information and the ability to participate in clinical trials. Participants emphasized that basic needs like food, housing, and transportation must be addressed before discussing participation in trials:

*"I mean, that's a that's a really a question. I'd be answering, seeing of those people who are of color that do participate in clinical trials maybe where they are on the economic scale. because it's a good point. If your necessity necessities and basic needs are not being met. You don't even really have the capacity to consider right often, because you're trying to just make sure that you can get to your next meal so it's hard to then think about even being a part of some type of clinical trial. so that's a good point. And obviously, if people don't have you know, adequate you know, safe and good housing, if they if they don't have food on their table. If they don't have electricity running through their house. If they don't have transportation those are going to create barriers for them to, even because you're trying to talk to them about a clinical trial and they're going to refocus making sure to get their lights turned on right or making sure they can have their next meal. So those are valid points, and I'd be interested in seeing. Okay? Well, then is it going to take a lot more than what we could be thinking to make sure that the necessities are being met to even be to have the conversation with them to think about something different than then being able to get the necessity and its necessities it needs."*

Another set of questions assessed barriers to participation in COVID-19 clinical trials. Participants identified a lack of trust, grief, and trauma from the pandemic as significant hindrances. The loss of family members to COVID-19 contributed to hesitancy, with participants expressing the need for informed discussions to alleviate concerns. Safety concerns stemming from the ongoing impact of the pandemic were also noted, indicating the importance of addressing psychological and emotional aspects when promoting

participation in clinical trials. Some remarks included:

*"Yes, it's basically the loss that they have experience of family members. I work with a lot of youth and as a part of a program that Well, a part of the program that I direct. We work with youth that have experience lost to Covid, and so I see it. I hear it almost daily. I've had Ladies are women that are in my mentoring group that lost their lives of Covid. So, their family members are dealing with it. So, it's. Basically, I think it's a good thing to have people to go through the clinical trial. It's just going to take information because of like, I said, the shock of the shock of some people who have had family members. girls who lost their mothers to Covid so it's like it's still that word that is very triggering when they hear it So yeah, but I think that with good information we may be able to get people to, maybe volunteer."*

*"I think. Just the safety of it because people have been so. I guess, traumatized by Covid in our neighbourhood, in our, you know and the neighbourhood community like basically it's scary. It's still scary, and people are now still going through counselling dealing with grief. It's a lot, and it's a lot unknown. But I believe that if some people or well informed you may be able to get a small amount, but I don't think it'll be a lot of people, a lot of us."*

Several barriers to clinical trial participation were identified, encompassing transportation challenges, environmental barriers associated with low income, concerns about side effects, lack of adequate incentives, lack of medication adherence, language barriers, limited access to appropriate technology, a lack of understanding about clinical trials, and a lack of trust in the government. These diverse impediments underscore the multifaceted challenges that must be addressed to enhance inclusivity and engagement in clinical research initiatives.

### Ethnic and Racial Disparities

Participants across both groups expressed concerns about racial and ethnic disparities in healthcare and research. One community leader highlighted the scarcity of racial and ethic minority representation among researchers and emphasized the impact of having researchers who look like the participants. The perception was that increased diversity among researchers could reduce hesitancy among racial and ethnic minorities to participate in clinical trials:

*"Another other thing I think relative to that is the number of people of color that are the researchers but when you have people who don't look like you asking you to participate in a clinical trial I think that in and of itself breeds a level of hesitancy on the part of people of color so if you have more students of color or researchers of color involved in the clinical and the research process and I think you have you cut down the gap because people have a have A at least an opportunity to see themselves as asking the question and there's a level of innate trust that you know goes along with seeing a person of color on the researcher side of the Ledger rather than the participant side of legend."*

Participants underscored the importance of addressing disparities, with a community leader citing an instance where information about blood pressure medications for Black or African Americans was lacking due to their underrepresentation in clinical trials:

*"Now when my primary care physician and I were trying to determine the best combination of drugs to control my high blood pressure, it was because African Americans don't participate in the clinical trials, so it took us a while to determine of all the medications that were available."*

A healthcare provider expressed enthusiasm for identifying and discussing racial and ethnic disparities, emphasizing the need for active participation by racial and ethnic minorities to influence interventions tailored to their specific needs:

*"The reason I'm so enthusiastic is that we think about racial disparities. It's incumbent upon us as people of color to participate. If not, we will always be behind when you look at you know hard, drug therapies are always on white males which do not apply to a black female. And so if I don't pave the way for the next steps for interventions to be better for someone who looks like me, then it does us no good. I mean doctors are essentially experimenting on a black female. When these drug therapies were oftentimes designed for white males that are completely different. Don't have the same lived experience, don't have the same level of stress. I could go on and on and on about that. And so that's why I'm absolutely resounding. Yes, that we have to get involved if we want to see a different outcome. If not the black communities of color are going to be left behind."*

While some participants expressed optimism about addressing these disparities through increased participation, others underscored the enduring impact of historical events like the Tuskegee experiment, they highlighted that understanding and addressing this history is essential for addressing the underlying causes of ongoing disparities.

*"I feel like it's kind of hard to forget the Tuskegee situation. Whoever is going out into the community first has to alleviate the fears surrounding that first. We can't approach them as if we are just trying to gather more African Americans so that we can have a better "head count" for a lack of a better term. We don't want the members of the community to think that we are going to get what we need and then forget about them."*

## Discussion

The first phase of our project involved hosting two focus groups conducted in various community settings in collaboration with

local organizations. The first focus group was designed to identify barriers to enrollment in COVID-19 clinical trials and gauge willingness to receive FDA-approved COVID-19 vaccines or those under emergency use authorization. The second focus group, involving community healthcare providers and leaders, focused on education and training strategies to increase enrollment and improve vaccine uptake.

An essential aspect of our research included training community members as health advisors or ambassadors. Focus group participants included the following types of community workers: pharmacists, physicians, nurses, student pharmacists from Florida A&M University (FAMU), social workers, psychologists, community health workers, community leaders, and faith-based leaders, healthcare workers from federally qualified health centers. Pharmacists, pharmaceutical scientists, student pharmacists, and other health professionals also engaged in the education and training of community workers on topics including, but not limited to, the biology of SARS-COV2, COVID-19 infection, COVID-19 vaccines, the significance of participating in COVID-19 clinical trials.

These individuals, residing in and respected by the community, play a vital role in conveying health education messages effectively. Their cultural knowledge and social consciousness uniquely position them to understand and address their communities' beliefs, attitudes, and behaviors, thereby contributing to changing perceptions regarding clinical trials and vaccination. One Florida community in Miami observed similar findings in a predominately Black or African American community faced with similar challenges [25].

Our research identified three pivotal themes surrounding perceptions of vaccinations within racial and ethnic minority communities: vaccine accessibility, vaccine hesitancy, and vaccine resistance. These factors collectively contribute to the challenges faced in increasing vaccination rates in this demographic [14]. Understanding and addressing these issues are crucial for developing effective strategies to promote vaccination uptake, particularly in the context of COVID-19.

We aimed to tackle these themes through a community-based participatory research (CBPR) approach. CBPR is a foundational strategy for engaging communities disproportionately affected by racial and ethnic disparities [22]. Overcoming mistrust is pivotal in fostering greater participation, especially in medical research or clinical trials. Proven techniques, including collaborative partnerships and equitable engagement, should be employed to educate and engage citizens facing inequalities in environmental exposure, economic burden, and healthcare access.

Adopting the CDC's Community-Based Organizations COVID-19 Vaccine Toolkit [23] and The Toolkit for Community and Faith-Based Organizations [26] as models for information dissemination and education was a step toward delivering accurate and up-to-date information. Employing a community navigator and a train-the-trainer approach, involving healthcare providers and educators from within the community, is effective in building relationships and understanding communication differences [27, 28].

Our study also explored community leaders' and healthcare providers' perceptions and experiences regarding clinical trials, focusing on participating in COVID-19 trials. The findings reveal significant variations in understanding, attitudes, and willingness to participate, shaped by a complex interplay of historical, social, and psychological factors. Participants' knowledge of clinical trials varied across groups. Community leaders generally viewed clinical trials as science experiments or research projects, with some recognizing their role in tailoring treatments to specific demographics. In contrast, healthcare providers demonstrated a more nuanced understanding, recognizing clinical trials as vital opportunities for treatment access. Despite this, only a few participants had prior experience with clinical trials, with most referencing trials unrelated to COVID-19. This distinction in perception highlights the importance of targeted education to bridge knowledge gaps between healthcare professionals and community leaders, ensuring both groups fully appreciate the potential benefits and risks of clinical trial participation.

A significant theme that emerged was the perception of information availability and access to clinical trials. Community leaders expressed diverse views, with some highlighting the need for more data on the potential impact of celebrity endorsements on vaccination rates among racial and ethnic communities. In contrast, others pointed to the general public's uncertainty, often fueled by commercials and social media. Healthcare providers also had varied experiences, with some relying on their alma maters for information while others independently sought and discerned information. Notably, one participant mentioned consistent outreach within their community through advertisements, billboards, and other sources, suggesting that information dissemination can vary significantly across communities. The lack of tailored public health messages for racial and ethnic communities may contribute to disparities in COVID-19 knowledge and behavior. Recent studies have found that when participants from racial and ethnic groups were randomly assigned to watch public health videos by a diverse group of physicians, knowledge gaps on COVID-19 symptoms, preventive behaviors, and transmission decreased [29,30].

When assessing willingness to participate in clinical trials, particularly those related to COVID-19, participants expressed more hesitancy than willingness. The uncertainty surrounding trial results was a common concern, reflecting broader anxieties about

the unknowns of clinical research. Despite this hesitancy, some participants identified factors that could enhance their willingness to participate, such as a preference for trials related to diseases they are passionate about. Enhancing racial and ethnic diversity in clinical trials and healthcare teams has been shown to improve vaccination rates in racial and ethnic communities by building trust, providing culturally relevant education, and reducing language barriers, thereby improving trial participation [31].

Barriers specific to COVID-19 clinical trials were also identified. The psychological and emotional toll of the pandemic, including grief and trauma from losing loved ones, played a role in participants' reluctance to engage in trials. Safety concerns, stemming from the ongoing impact of COVID-19, underscored the need for informed discussions to alleviate fears and address the lingering effects of the pandemic. Access to clinical trial information also emerged as a critical barrier. Participants pointed to inadequate outreach and a lack of clear, accessible information about available trials. Socioeconomic factors further exacerbated these challenges, as individuals with lower income levels often struggle to meet basic needs such as food, housing, and transportation, making participation in clinical trials a lower priority [32]. These diverse impediments highlight the multifaceted challenges that must be addressed to enhance inclusivity and engagement in clinical research.

A recurrent theme across both community leader and healthcare provider groups was the issue of trust. Participants cited this distrust as a primary factor deterring clinical trial participation [33]. Additionally, the lack of diversity among researchers was noted as a barrier, with several participants expressing a belief that increased representation of minorities in research roles could help mitigate hesitancy among minorities. Racial and ethnic community leaders felt more comfortable participating in clinical trials led by an HBCU. They all agreed that the long-standing relationships between the community and HBCUs, along with the established credibility of HBCU faculty within these communities, would enhance their willingness to participate in clinical trials.

Despite the prevailing hesitancy, some participants identified factors that could increase their willingness to participate in clinical trials. These included a preference for trials related to diseases they were passionate about and the presence of researchers who reflected their racial or ethnic background. There was also recognition of the importance of active participation by people of color to ensure that clinical interventions are tailored to their specific needs. Participants expressed optimism about addressing healthcare disparities through increased trial participation, though they acknowledged that overcoming the historical and ongoing mistrust would be challenging. The enduring impact of events like the Tuskegee experiment was cited as a reason for the continued disparities in healthcare and clinical research participation [15, 34]. This suggests that sustained trust-building initiatives within these communities must accompany efforts to increase enrollment of diverse populations in clinical trials.

## Conclusion

In conclusion, our comprehensive approach, rooted in CBPR and incorporating community engagement, education, and outreach, sought to address the multifaceted challenges of racial and ethnic communities clinical trial participation, vaccine accessibility, hesitancy, and resistance within minority communities. By fostering trust, providing accurate information, and actively involving community members, we aspire to contribute to increased participation in clinical trials, improved vaccination rates, and improved health outcomes in these communities.

Racial and ethnic minority community leaders felt more comfortable participating in clinical trials led by an HBCU. They all agreed that the relationships with the community and the credibility of HBCU faculty would enhance their willingness to participate in clinical trials.

## Funding

This project is supported by the Food and Drug Administration (FDA) Office of Minority Health and Health Equity of the U.S Department of Health and Human Services (HHS) as part of a financial assistance award [FAIN] totalling $707280.00 with 100 percent funded by FDA OMHHE/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

## Ethics Approval

This study was reviewed and approved by Florida A&M University Institutional Review Board

**Conflict of Interest**: All of the authors have no conflicts of interest to disclose.

**Informed Consent**: Informed consent was obtained from all individual participants included in the study.

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