# Stakeholder Perspectives on Enhancing Minority Participation in Clinical Research: Lessons from COVID-19 Vaccine Trials


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## Introduction

The underrepresentation of minority populations in clinical research compromises health equity and the generalizability of findings. While the NIH Revitalization Act of 1993 and 2022 FDA guidelines mandated the inclusion of diverse groups, significant barriers remain. During the COVID-19 pandemic, the Lundquist Institute achieved high minority enrollment (55%–78%) in the AZD1222 vaccine trial through collaboration with a Community Consultant Panel (CCP). This study investigates the specific factors that influence minority participation from the perspective of various stakeholders.

## Aims and Objectives

- To identify and rank the primary barriers and facilitators to minority enrollment in clinical trials.
- To compare the perspectives of three key stakeholder groups: Infectious Disease Investigators, Clinical Research Staff, and a Community Advisory Board (CAB).
- To provide actionable, priority-based recommendations for increasing inclusivity in future clinical research.

## Methods

- Survey Design: A structured 20-question survey using a Likert scale (1–5), categorized into three themes: Logistical (9 questions), Information/Engagement (5 questions), and Cultural/Community factors (6 questions).
- Participants: 39 total stakeholders, including 7 Investigators, 12 Research Staff, and 20 CAB members (predominantly people of color).
- Data Collection: Distributed via in person meeting and Google Forms through email and Zoom; data collected over two weeks.
- Analysis: Quantitative analysis using mean, standard deviation, and median (IQR) to rank-order the significance of factors for each group.
- Ethics: Deemed IRB exempt as it involved educational surveys without direct patient interaction.

| Questions |
|---|
| 1. Access to clinical site (ie. distance to home) |
| 2. Access to reliable transportation (eg. uber or public transit) |
| 3. Access to healthcare infrastructure (ie. having a primary provider or site proximity to hospital) |
| 4. Research site directing to additional resources (eg. mental health service or food banks) |
| 5. Financial Incentives/reimbursement for participation |
| 6. Food and beverage availability on site |
| 7. Child care services on site |
| 8. Trial Duration (ie. how many weeks it is conducted) |
| 9. Difficulty of protocol (ie. length of visits/number of tests) |
| 10. Knowledge of condition or investigational drug |
| 11. Quality/availability of existing treatments |
| 12. Marketing and advertising of trials |
| 13. Reputation of clinical site in the community |
| 14. Clear communication and positive patient interactions |
| 15. Family Support (eg. approval or reminder to adhere to study) |
| 16. CAB/community engagement in protocol development and/or study participation |
| 17. Language/translation services |
| 18. Diversity of staff |
| 19. Cultural sensitivity of staff |
| 20. LGBTQ+ inclusive |

Table 1. Questions distributed within the survey. Purple, logistical factors; green, information and engagement; and blue, culture and community.

## Results

| Mean data of categorized responses | | | | | | |
|---|---|---|---|---|---|---|
| Group | Logistical Factors | SD | Information and Engagement | SD | Cultural and Community | SD |
| CAB | 4.0 | 1.0 | 4.5 | 0.6 | 3.9 | 1.3 |
| Research Staff | 4.3 | 0.9 | 4.5 | 0.8 | 4.5 | 0.8 |
| Investigators | 4.1 | 1.0 | 3.9 | 1.1 | 4.6 | 0.7 |
| Total | 4.1 | 1.0 | 4.4 | 0.8 | 4.2 | 1.1 |

Table 2. The mean (+SD) of responses of each group on a categorized set of questions.

| Top and Bottom 3 Factors by Mean | | |
|---|---|---|
| Group | Top 3 Factors | Bottom 3 Factors |
| CAB | 10, 2, 11 | 8, 15, 7 |
| Staff | 17, 14, 19 | 12, 4, 7 |
| Investigators | 19, 17, 20 | 7, 3, 12 |

Table 3. Each group had all their mean responses from each question ranked in order.

- **Response Rates:** High engagement across all groups: Investigators (100%), Research Staff (100%), and CAB (95%).
- **Logistical Factors:** Consistently ranked high by all groups (means between 4.0 and 4.3). Research staff identified these as the primary concern.
- **Information vs. Culture:** Investigators and Research Staff rated **Cultural and Community factors** more highly, whereas the **CAB** placed a higher priority on **Information and Engagement** (e.g., knowledge of the drug/condition).
- **Commonalities:** All groups ranked **childcare** as one of the least important factors affecting recruitment.
- **CAB Priorities:** Uniquely emphasized reliable transportation (ride-sharing/public transit) and informed decision-making through education.

## Conclusions

Addressing diversity in clinical trials requires a multifaceted approach tailored to specific stakeholder insights. While investigators focus on cultural competence, the community (CAB) prioritizes tangible logistics (transportation) and clear information. The success of the COVID-19 trials at Lundquist suggests that involving community representatives early in the recruitment process is vital for bridging the gap between research teams and local minority populations.

## References


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