



# WHAT DOES COMMITMENT TO DIVERSITY IN CLINICAL RESEARCH LOOK LIKE IN PRACTICE: PROTOCOL DESIGN, PATIENT, AND STAFFING CONSIDERATIONS

Aisha T. Langford, PhD, MPH  
Assistant Professor of Population Health  
Co-Director, CTSI Recruitment and Retention Core  
[aisha.langford@nyulangone.org](mailto:aisha.langford@nyulangone.org)



# Clinical Trials: Diversity in Trial Type, Phase, and Target Populations



# Fairness and Inclusion in COVID-19 Trials

**HealthAffairs** TOPICS JOURNAL BLOG

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## Clinical Trials For COVID-19: Populations Most Vulnerable To COVID-19 Must Be Included

Aisha T. Langford, Alison Bateman-House

JUNE 12, 2020 10.1377/hblog20200609.555007



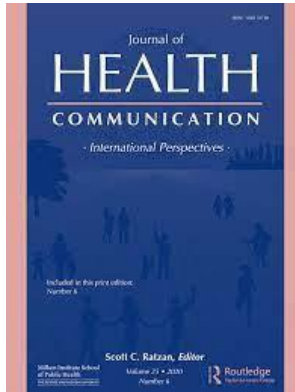
<https://www.healthaffairs.org/doi/10.1377/hblog20200609.555007/full/>, Accessed 10/9/2022

# Strategies to Enhance Inclusion of Vulnerable Groups in COVID-19 Trials



- Pay attention to inclusion and exclusion criteria
- Ensure that people are aware of and explicitly invited to participate when eligible
- Conduct trials where people live or get their care
- Minimize participation burden

<https://www.healthaffairs.org/doi/10.1377/hblog20200609.555007/full/>, Accessed 10/9/2022



## Journal of Health Communication >

International Perspectives

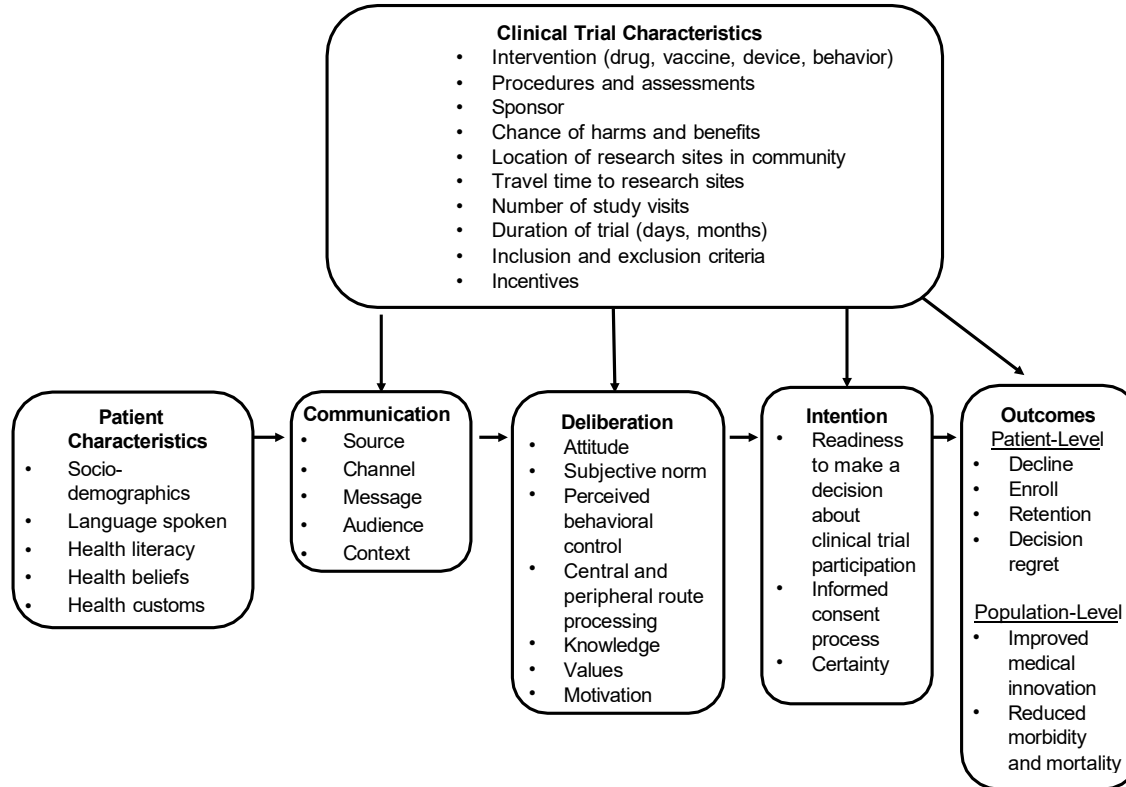
Volume 25, 2020 - Issue 10: Vaccine Communication in a Pandemic: Improving Vaccine Literacy to Reduce Hesitancy, Restore Trust and Immunize Communities

# Health Communication and Decision Making about Vaccine Clinical Trials during a Pandemic

Aisha T. Langford  

Pages 780-789 | Published online: 13 Mar 2021

# General Model of Clinical Trial Participation: Health Communication and Decision Making Considerations



# The ASK Approach to Enhancing Clinical Trial Participation

<b>A</b>	<b>Assume</b> that all patients will want to know their options.
<b>S</b>	<b>Seek</b> the counsel of stakeholders.
<b>K</b>	<b>Know</b> your numbers.

Langford AT (2021). Health communication and decision making about vaccine clinical trials during a pandemic. *Journal of Health Communication*. doi: 10.1080/10810730.2020.1864520.

# Stakeholders may include, but not limited to:

- Researchers
- Patients
- Caregivers
- Community health workers
- Community-based organizations
- Faith-based organizations
- Internal clinicians
- External referring clinicians
- Administrators
- Communication and marketing professionals
- Health information technology professionals
- Institutional review board professionals
- Pharmaceutical companies
- Media partners
- Policymakers



# Know Your Numbers

Key numbers to track in a clinical trial include:

- Number of potentially eligible patients or “pool of patients”
- Number of people invited by different channels (patient portals vs. mailed letters)
- Number of responses by different channels (patient portals, social media, email)
- Number of interested, but not eligible patients
- Number of declines by eligible patients
- Number of enrolled patients

## At What Cost to Clinical Trial Enrollment? A Retrospective Study of Patient Travel Burden in Cancer Clinical Trials

HALA T. BORNO,<sup>a</sup> LI ZHANG,<sup>a,b</sup> ADAM SIEGEL,<sup>a</sup> EMILY CHANG,<sup>b</sup> CHARLES J. RYAN<sup>a,b</sup>

<sup>a</sup>Department of Medicine, Division of Hematology and Oncology, and <sup>b</sup>Helen Diller Family Comprehensive Cancer Center, University of California San Francisco, San Francisco, California, USA

*Disclosures of potential conflicts of interest may be found at the end of this article.*

**Key Words.** Representativeness in clinical trials • Recruitment science • Travel distance • Health care costs • Cancer clinical trial disparities

# Context and Setting

- Cancer patients in UC San Francisco Clinical Trial Management System database
- Enrolled in a clinical trial for breast, genitourinary, or gastrointestinal malignancy between 1993 and 2014

# Outcome of Interest

- Distance traveled from home to center calculated using a GoogleMaps application programming interface.

# Results

- 1,600 patients were enrolled in breast (55.8%), genitourinary (29.4%), or gastrointestinal (14.9%) cancer CTs
- Overall median unidirectional distance traveled from home to study site was 25.8 miles (interquartile range [IQR] 11.5-75.3)

## Results Cont.

- Longest distance traveled was for NIH-sponsored trials, with a median of 39.4 miles ( $p < .001$ ).
- Phase I (8.4%) studies had the longest distance traveled, with a median of 41.2 miles ( $p = .001$ ).

## Results Cont.

- Patients from lower-income areas ( $n = 799$ ) traveled longer distances compared with patients from higher-income areas ( $n = 773$ ; 58.3 vs. 17.8 miles, respectively;  $p < .001$ )



**JAMA Network Open**

**Original Investigation** | Diversity, Equity, and Inclusion

February 14, 2022

# Comparison of Racial, Ethnic, and Geographic Location Diversity of Participants Enrolled in Clinic-Based vs 2 Remote COVID-19 Clinical Trials

Jenell Stewart, DO, MPH<sup>1</sup>; Meighan L. Krows, BA<sup>1</sup>; Torin T. Schaafsma, MPH<sup>1</sup>; [et al](#)

» [Author Affiliations](#) | [Article Information](#)

*JAMA Netw Open.* 2022;5(2):e2148325. doi:10.1001/jamanetworkopen.2021.48325



# Question

Were racial, ethnic, and geographic location demographics of participants enrolled in 2 remote clinical trials with online recruitment more diverse compared with those of participants in a clinic-based COVID-19 study?

# Context and Setting

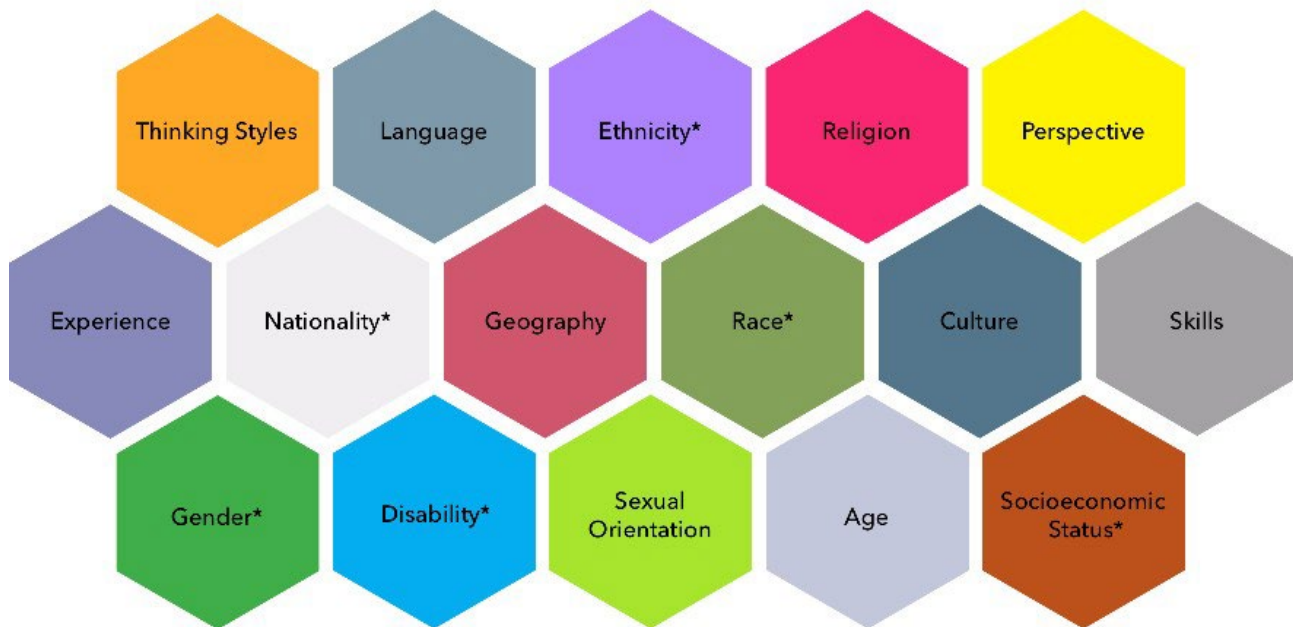
- Cohort study
- Secondary analysis of 1410 participants enrolled in 3 COVID-19 studies conducted in 2020 during the early COVID-19

# Key Findings and Conclusion

- Remote clinical trials with online recruitment had increased racial, ethnic, and geographic location diversity among study participants

*“These findings suggest that remote clinical trials with online advertising may be considered as a strategy to improve diversity among clinical trial participants.”*

# Many Types of Diversity



- A diversity of perspectives and lived experiences is fundamental to achieving research and training excellence.

# Equity: One (of many) definitions

- The removal of systemic barriers and biases enabling all individuals to have equal opportunity to access and benefit from the program.

# Inclusion: One (of many) definitions

- The practice of ensuring that all individuals are valued and respected for their contributions and are equally supported.

# Group Question: How would you ensure that all potentially eligible people are invited to consider clinical trials?



# Opt Out vs. Opt In Systems





# Example of an Opt Out System



## NYU Langone Medical Center Notice of Privacy Practices

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

We may also use or share your information to contact you:

- about health-related benefits or services.
- about your upcoming appointments.
- to see if you would like to take part in research projects.
- about fundraising for NYU Langone.

# Screenshot from my own patient record

The screenshot displays the MyChart interface for a patient named Aisha. The top navigation bar includes 'Menu', 'Appointments & Visits', 'Messages', 'Test Results', and 'Medications'. The main content area is titled 'Research Studies' and features a 'Participation Preferences' section. This section asks, 'May we contact you about opportunities to participate in research studies?' and provides two buttons: 'OK to contact' (highlighted in blue) and 'Do not contact'. Below this, there is a link to 'Notifications' and a 'Go to profile' button. To the right, a 'Participation Preferences' sidebar explains that preferences help with research opportunities and includes a 'Related Links' section with a bell icon and text about receiving NYU Langone Health MyChart notifications for research. The main area also lists 'Active Studies' (COVID-19 Vaccine Trial, On-Study) and 'Other Studies' (The Factors Influencing Reproductive success and time to pregnancy study (NYU First), Do not contact this patient). A 'Clinical Trials' section at the bottom provides information about the research community and a link to 'View All Clinical Trials'.

MyChart by Epic Log out

Menu Appointments & Visits Messages Test Results Medications Aisha

## Research Studies

### Participation Preferences

May we contact you about opportunities to participate in research studies?  
You can choose how to be contacted in [Notifications](#).

Update your profile to let us know the types of research you may be interested in.

### Participation Preferences

Your preferences will help us let you know about research opportunities that might interest you. Your care team might discuss additional opportunities with you.

### Related Links

Specify how you would like to receive NYU Langone Health MyChart notifications for research

### Active Studies

**COVID-19 Vaccine Trial** **On-Study**  
The NYU Langone Vaccine Center is seeking healthy adult volunteers who are interested in participating in clinical resear...

### Other Studies

**The Factors Influencing Reproductive success and time to pregnancy study (NYU First)** **Do not contact this patient**  
New NYU study for women planning pregnancy! Interested? At a recent doctor's visit you indicated that you were thinkin...

### Clinical Trials

Study participants are a vital part of our research community. By participating in a clinical trial, you can help our scientists translate scientific breakthroughs into innovative medical care.

[View All Clinical Trials](#)

# Example of an Opt In System



Make a positive  
impact by  
volunteering for  
research

Join Now!

## What is ResearchMatch?

ResearchMatch is a nonprofit program funded by the National Institutes of Health (NIH). It helps to connect people interested in research studies with researchers from top medical centers across the U.S.

Get connected to research on many different health conditions - through ResearchMatch.

Learn More



# Example Invitation from ResearchMatch.org

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## ResearchMatch: You may be a good match for this study!

1 message

ResearchMatch <no-reply@mail.researchmatch.org>

Reply-To: info@researchmatch.org

To: aishalangford@gmail.com

Thu, Sep 1, 2022 at 11:39 AM



A research team with George Washington University in Washington, DC, believes you might be a good match for the following study:

You are invited to participate in a research study that seeks to understand attitudes towards women and the effects on mental health in the United States. The study involves a single survey that will be completed in one sitting, taking approximately 15 minutes. Eligible participants are ciswomen, aged 18 years or older, who are currently living in the United States and who speak English. Participation is voluntary and you will not be compensated; however, your participation in this study will benefit science and humankind to better understand how attitudes toward women impact health.

If you are interested in this study and having the research team contact you directly, please select the "Yes, I'm interested" link below. By clicking the "Yes, I'm interested" link, your contact information will be released to the research team. If you select the "No, thanks." link or do not respond to this study message, your contact information will not be released to the research team.

[Yes, I'm interested!](#)

[No, thanks.](#)

# Who is in the Biomedical, Clinical, Behavioral and Social Sciences Research Workforce?



Underrepresented  
Racial and Ethnic  
Groups



Individuals with  
Disabilities



Individuals from  
Disadvantaged  
Backgrounds



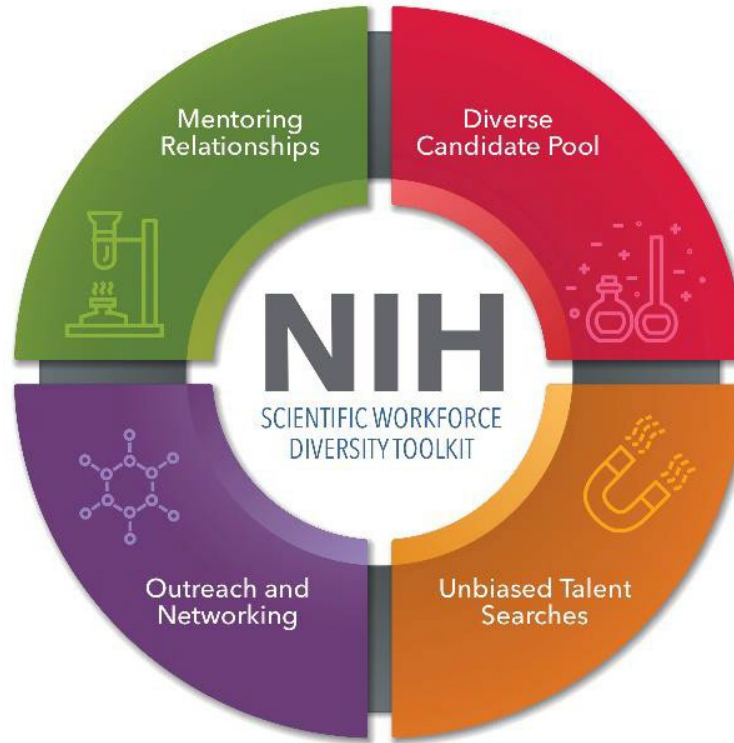
Women in the  
Biomedical  
Workforce

<https://extramural-diversity.nih.gov/diversity-matters/get-the-facts>, accessed 8/27/2021

# Getting People in the Door: Recruitment



# Strategies to Enhance Scientific Workforce Diversity



# Strategies for Promoting Diversity

- **Systematically review** hiring and promotion procedures and policies
- **Be transparent:** collect and publicize aggregate diversity metrics
- **Commit resources** and **provide diversity tools** to Divisions and Departments
- **Evaluate impact** and adjust strategy if needed



# Strategies for Promoting Diversity

- **Review and ensure** equality in salary and resources
- **Ensure** width, breadth, and fairness in talent searches
- **Sponsor** all faculty through promotion for awards and inclusion in professional networks

# Strategies for Promoting Diversity

- **Endorse and promote** work-life balance resources for all faculty
- **Conduct anonymous climate surveys** and make changes if necessary

[https://diversity.nih.gov/sites/coswd/files/images/SWD\\_Toolkit\\_Interactive-updated\\_508.pdf](https://diversity.nih.gov/sites/coswd/files/images/SWD_Toolkit_Interactive-updated_508.pdf),  
accessed 3/9/21

# Conducting Unbiased Talent Searches

- Develop **clear criteria** and **standards** for the position before anyone is recruited or contacted
- Create a clear **evaluation system** in advance and avoid global scoring
- Conduct **anonymous voting**, if the size of the pool is large enough
- Ensure that search committees are **diverse**

# Unintended Effects of Unpaid Internships



**Ryan Ken**  
@Ryan\_Ken\_Acts



The t is many unpaid internships are the grooming period for the abuse you will endure as an employee. It's a period of testing your limits. The internship itself can be an assessment of how willing you are accept financial abuse. Pennies sound like a lot after working for free.

8:29 PM · Mar 2, 2021 · Twitter for Android



**Ryan Ken**  
@Ryan\_Ken\_Acts



Replying to [@Ryan\\_Ken\\_Acts](#)

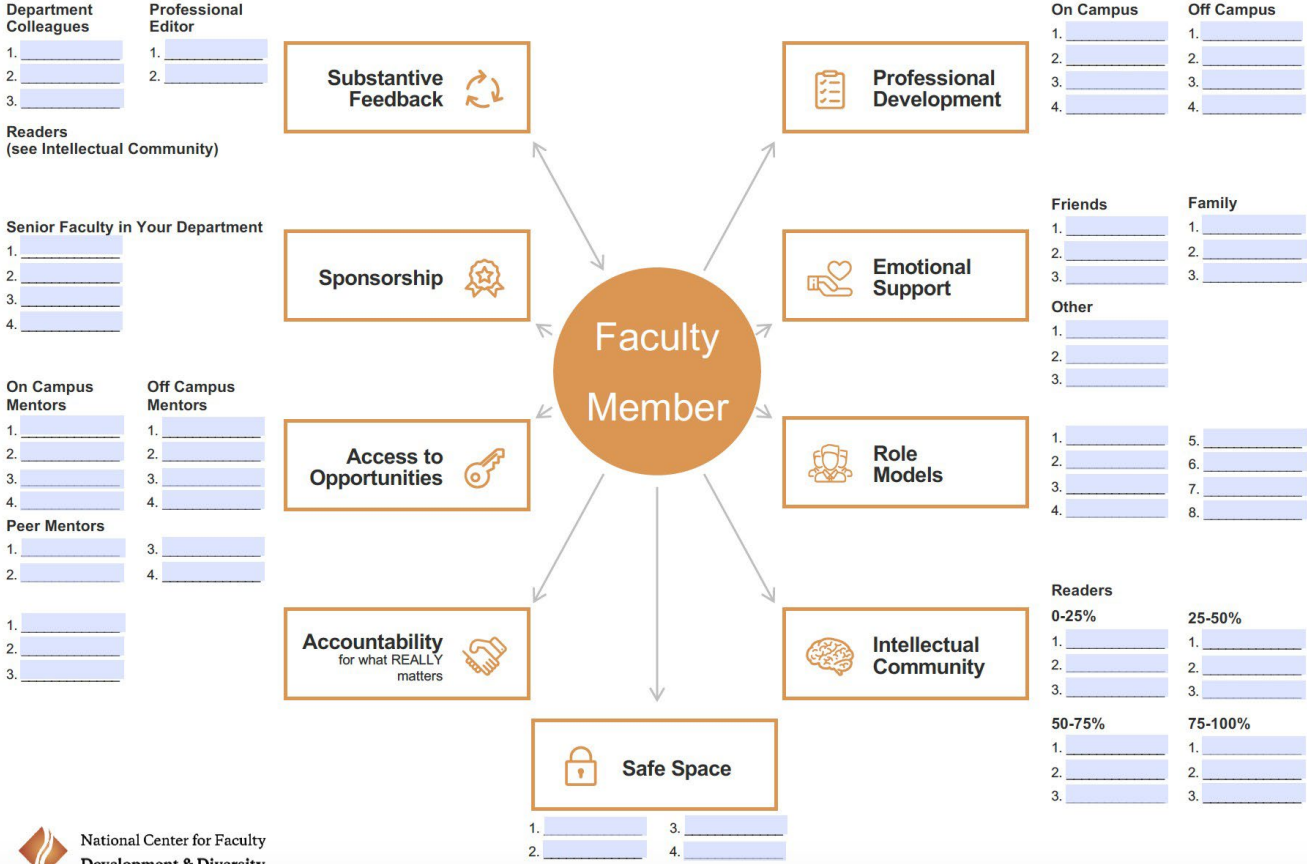
Some of my mentors saw me as ungrateful for opportunities, but it was financially impossible for me to devote hours to free labor. These systems were designed for ppl with money and the pressure to "perform" wealth can produce compound financial obstacles for working class ppl

9:07 PM · Mar 2, 2021 · Twitter for Android

# Keeping People in the Door: Retention



# NCFDD Mentoring Map



# Dear Kerry Ann: Can I Mentor African-American Faculty?



02/17/2016

*Dear Kerry Ann,*

*I enjoy reading your columns. I'll be brief: I don't know how to mentor scholars of color in my department. I'm a white guy, and I don't experience the same things minority faculty members do in the classroom or on the campus. Because of that, I feel awkward trying to give them advice. I have a new mentee (a brand-new tenure-track faculty member, who is African-American) and I want to be helpful as her department mentor, but I honestly don't know how. Can I mentor African-American faculty effectively? Or should I try to connect her with a tenured African-American scholar in another department. (We don't have any.)*

*Sincerely,*

*Unsure How to Mentor*

<https://www.facultydiversity.org/news/dearkerryann31>, accessed 8/26/2021

# What limiting beliefs are driving your awkward feelings?

Here are a few possible limiting beliefs that may be at work:

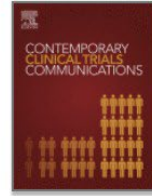
- Faculty of color can *only* be mentored by other faculty of color.
- Faculty of color *only* need mentoring on issues related to race.
- There are no needs that faculty of color have that can be met by you.
- Mentoring means giving advice to mentees based on your personal experience.





# Contemporary Clinical Trials Communications

Volume 15, September 2019, 100424



Research paper

## Knowledge and use of recruitment support tools among study coordinators at an academic medical center: The Novel Approaches to Recruitment Planning Study

Ebony Scott <sup>a</sup>  , Bryan McComb <sup>a</sup> , Howard Trachtman <sup>a</sup> , Lois Mannon <sup>a</sup> , Peri Rosenfeld <sup>b</sup> , Rachel Thornton <sup>a</sup> , Nassira Bougrab <sup>a</sup> , Scott Sherman <sup>a, c</sup> , Aisha Langford <sup>a</sup> 

# Background & Methods

- Study coordinators play an essential role on study teams; however, there remains a paucity of research on the supports and services they need to effectively recruit and retain study participants.
- A cross-sectional survey was conducted with 147 study coordinators from NYU Langone Health

# Perspectives about the importance of participant-study coordinator concordance

- Respondents were asked to assess the importance of participant-study coordinator concordance regarding:
  - Age
  - Gender
  - Race/ethnicity
  - Language spoken

**Table 3**

Participant/Study Coordinator Concordance	1 (Not at all important)	2	3	4	5 (Very important)
Age	35 (23.8%)	30 (20.4%)	41 (27.9%)	26 (17.7%)	14 (9.5%)
Gender	54 (36.7%)	33 (22.4%)	41 (27.9%)	15 (10.2%)	2 (1.4%)
Race/ethnicity	37 (25.2%)	23 (15.6%)	44 (30%)	28 (19.0%)	14 (9.5%)
Language	2 (1.4%)	5 (3.4%)	17 (11.6%)	35 (23.8%)	87 (58.2%)

# Emerging Questions and Group Discussion

- What aspects of diversity should be prioritized in clinical trials?
- What is the ideal construction of a study team?



# Thank You

Aisha T. Langford, PhD, MPH  
Assistant Professor of Population Health  
Co-Director, CTSI Recruitment & Retention Core  
NYU Grossman School of Medicine  
E-mail: [Aisha.Langford@nyulangone.org](mailto:Aisha.Langford@nyulangone.org)

