

RESEARCH PROFESSIONALS NETWORK

CHAMPIONING A CULTURE OF INCLUSION: RESEARCH DESIGN AND PARTICIPATION

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PRESENTATION OVERVIEW

Regarding inclusion in research participation, we want you to know...

Overview

- Social Determinants of Health
- Health Disparities Data
- Community Engagement Principles

Study Recruitment

- Trust Building
- Cultural Sensitivity and Health Literacy
- Applied Community Engagement Principles
- Study Recruitment Considerations

Study Design

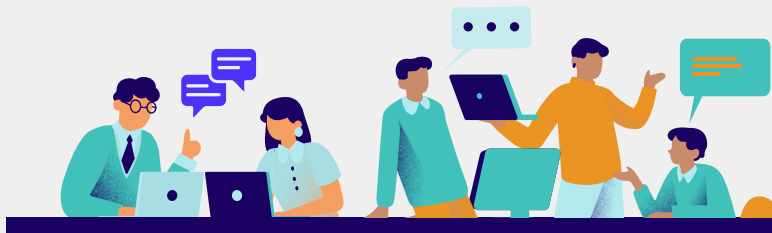
- Budgeting for Recruitment
- Designing Informed Consent/Surveys/Questionnaires
- Motivations for and Barriers to Participating in Research
- Disseminating Research Findings

WORD CLOUD


When you think of diversity
and inclusion in research,
what word comes to mind?

www.polllev.com/carolinar327 or TEXT carolinar327 to 22333

Poll Everywhere QR Code:




AUDIENCE ACTIVITY



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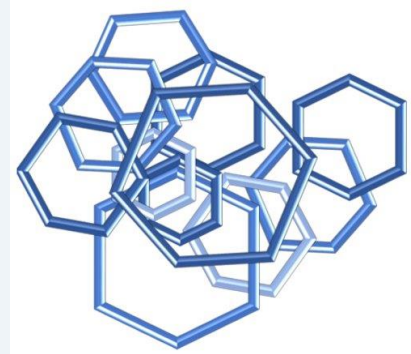
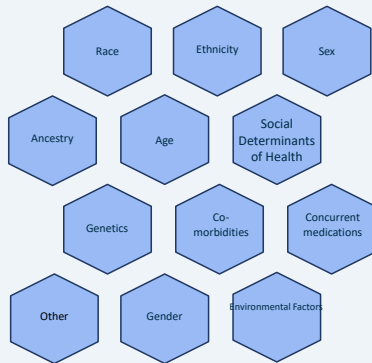
When poll is active respond at PollEv.com/carolinar327 Send **carolinar327** to **22333**



When you think of diversity and inclusion in research, what word comes to mind?

Nobody has responded yet.
Hang tight! Responses are coming in.

Diversity Exists Across Many Dimensions



MRCT Center, 2021

Why is this all so important?

Ethical Considerations

Belmont Report

- Concept of fairness

Individual Level and Population Level

- Access to care
- Evidence base relevant to care

Public opinion and trust can be compromised

Scientific Considerations

Robust and Complete Data

Generalizable Results

Improved Scientific Knowledge

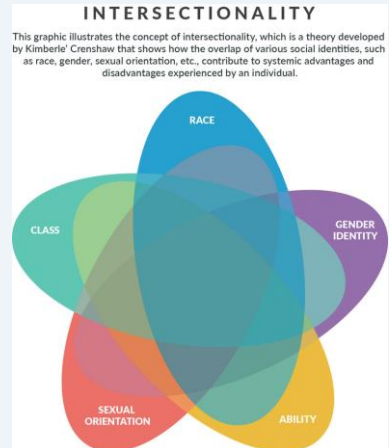
Special Populations and Geographic Locations

Special Populations

- Racial and Ethnic Minorities
- Older Adults
- Those living in rural areas
- Women
- Those with disabilities
- LGBTQIA+: sexual orientation and gender identity

Geographic Locations

- University of Florida (Florida)
- Medical University of South Carolina (South Carolina)
- Boston University (Massachusetts)
- University of Vermont (Vermont)



Areas Of Consideration

"UNCONSCIOUS BIAS" VS. DISRUPTING OUR BIAS	"MINORITY GROUP" VS. HISTORICALLY UNDERSERVED POPULATIONS	"HISTORICALLY UNDERSERVED POPULATIONS" VS. "HISTORICALLY UNDERRECOGNIZED POPULATIONS"	SEX VS. GENDER
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REMEMBER THAT NOT ALL EXPERIENCES
ARE MONOLITHIC



Social Determinants of Health



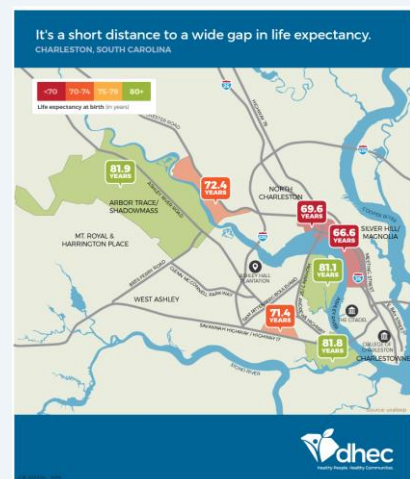
Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Retrieved [September 5, 2023], from <https://health.gov/healthypeople/objectives-and-data/social-determinants-health>

- Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.
- One of three priority areas for Healthy People 2030
 - Healthy Equity and Health Literacy are the other two

What is the problem?

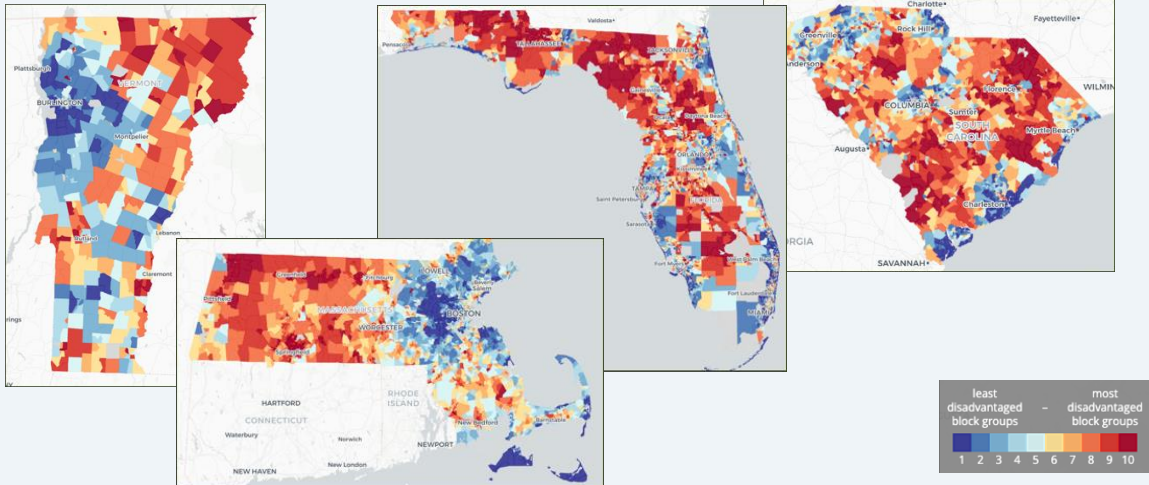
Health Disparity Data Points

- Charleston, South Carolina
 - Life expectancy differences (shown in graphic)
- Gainesville, Florida
 - The analysis of top causes of death revealed that mortality rates in Alachua County were higher than state averages for diseases, such as cancer and diabetes. Breaking down this data by racial group revealed distinct patterns of disease. (Alachua County Community Health Needs Assessment, 2020)
- Boston, Massachusetts
 - A nearly 23-year gap between a census tract in Back Bay where the life expectancy is 91.6 years and a census tract in Roxbury where life expectancy is 68.8 years. (Boston Public Health Commission, 2023)
- Burlington, Vermont
 - The annual median income in Chittenden County in 2021 was \$36,310 for Black or African American households and \$50,625 for Asian households compared to \$79,133 for white, non-Hispanic households. (U.S. Census 2020 5-year estimates)



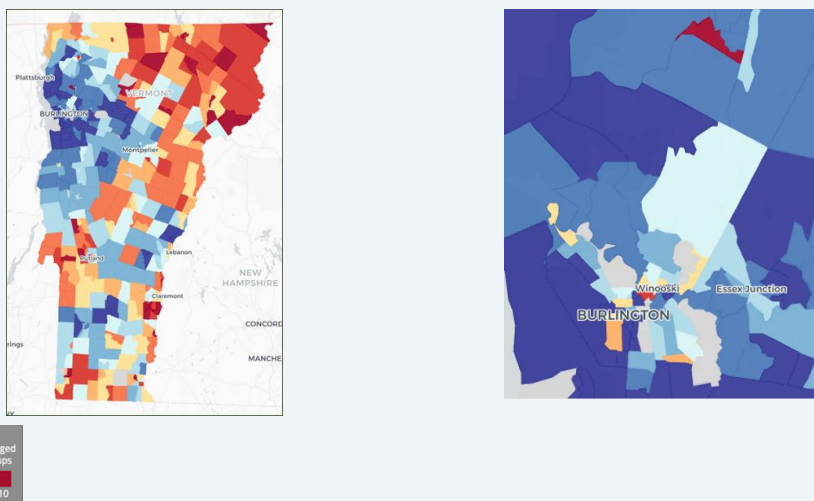
S.C. Department of Health and Environmental Control, 2023

Area Deprivation Index (ADI)



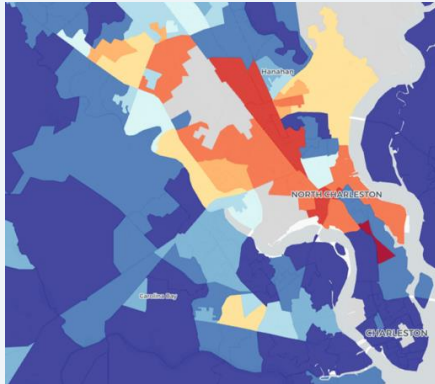
<https://www.neighborhoodatlas.medicine.wisc.edu/mapping%E2%80%8B8B>

Area Deprivation Index (ADI)



<https://www.neighborhoodatlas.medicine.wisc.edu/mapping%E2%80%8B8B>

Health Disparities through ADI: Life Expectancy



Introduction to Community Engagement

CDC Community Engagement Definition:

“The process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people”

Domains and Indicators of Meaningful Engagement

- Strengthened partnerships and alliances
- Expanded knowledge
- Improved health and health care programs and policies
- Thriving communities

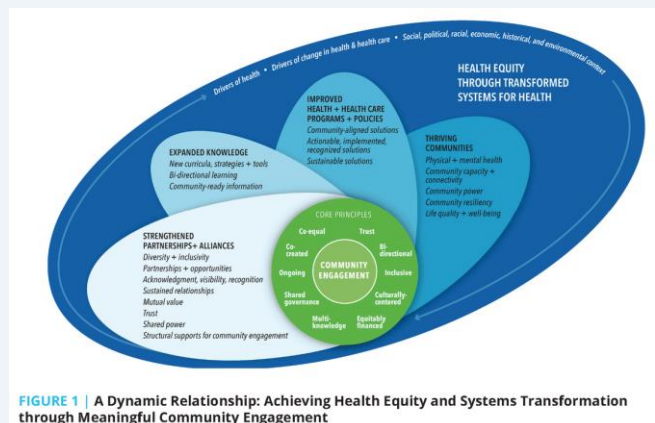


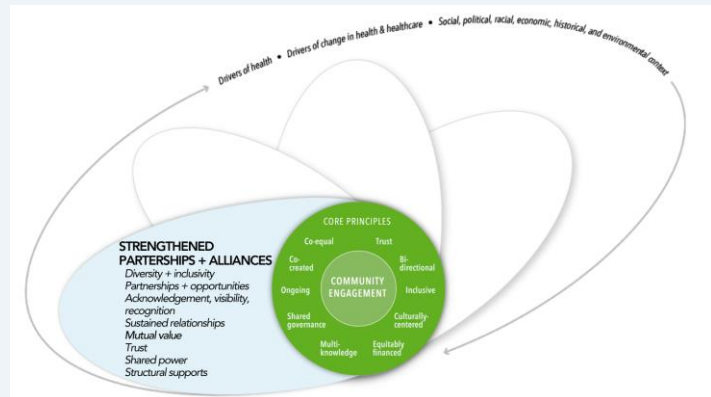
FIGURE 1 | A Dynamic Relationship: Achieving Health Equity and Systems Transformation through Meaningful Community Engagement

Community Engagement

Strengthened Partnerships and Alliances

Eight indicators:

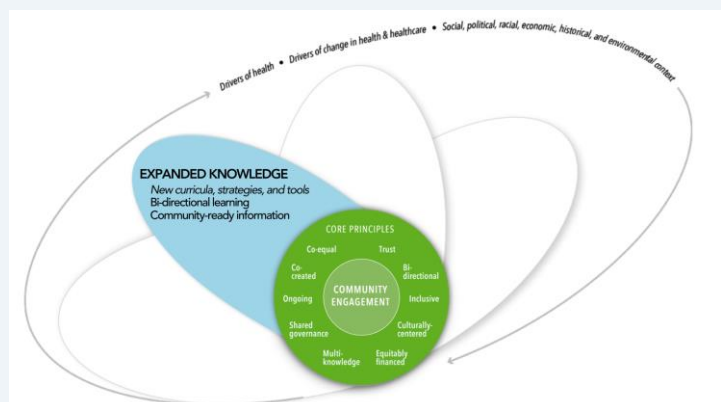
- Diversity and inclusivity
- Partnerships and opportunities
- Acknowledgment, visibility, and recognition
- Sustained relationships
- Mutual value
- *Trust*
- Shared power
- Structural supports for community engagement



Community Engagement

Expanded Knowledge:

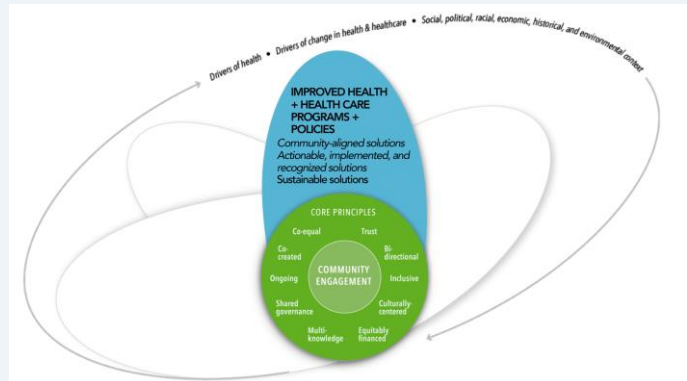
The creation of new insights, stories, resources, and evidence, as well as the formalization of respect for existing legacies and culturally embedded ways of knowing that are unrecognized outside of their communities of origin.



Community Engagement

Improved Health and Health Care Programs and Policies

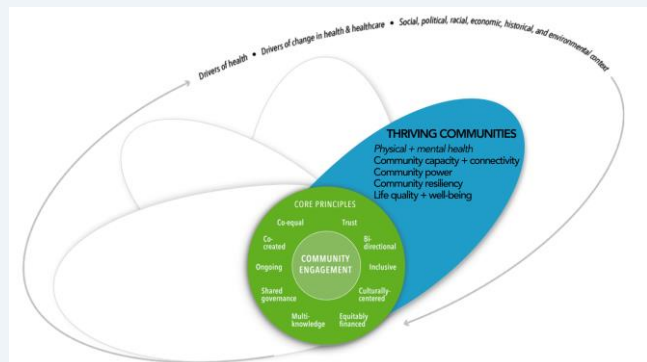
This is the stated goal of many partnerships; however, creating programs and policies that communities want and will use—a prerequisite to effectiveness in real-world settings—requires alignment between those who design programs, services, and policies and those who are expected to use them



Community Engagement

Thriving Communities

Physical and Mental Health Indicator addresses: shared decision-making in health care treatments and priorities; increased confidence and capacity to make decisions that improve an individual's own health; and increased resiliency.



Community Engagement



The fundamental question is not whether entities think they are engaging communities, but whether communities feel engaged.

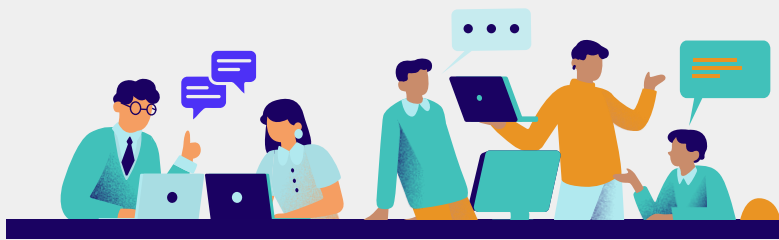
nam.edu/Perspectives

Organizing Committee for Assessing Meaningful Community Engagement in Health & Health Care Programs & Policies. 2022. Assessing Meaningful Community Engagement: A Conceptual Model to Advance Health Equity through Transformed Systems for Health. *NAM Perspectives*. Commentary, National Academy of Medicine, Washington, DC. <https://doi.org/10.31478/202202c>.

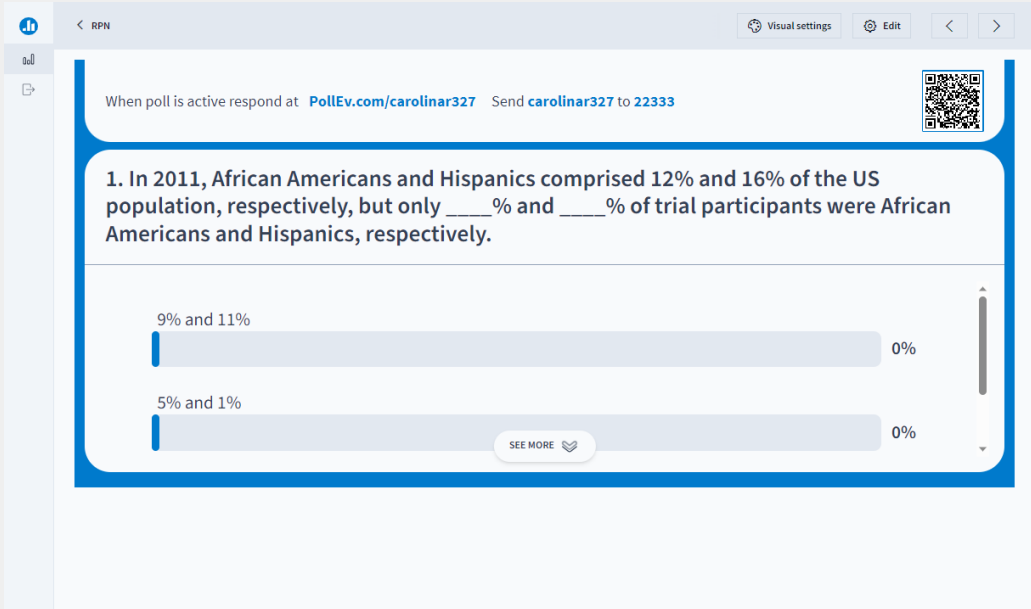
POLL EVERYWHERE ACTIVITY: Health Disparities Data Points

www.pollev.com/carolinar327 or TEXT carolinar327 to 22333

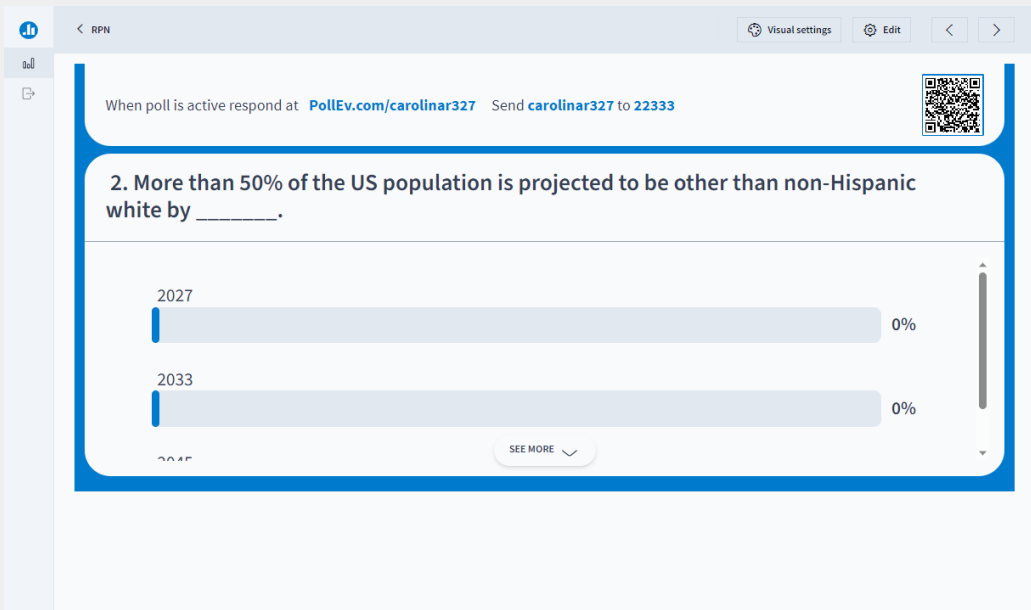
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In 2020, industry-sponsored clinical trials that supported Food and Drug Administration (FDA) approval of new molecular entities and original therapeutic biologics included _____% Black or African American, _____% Asian, and _____% Hispanic or Latino part

(A) 8% Black or African American, 6% Asian, and 11% Hispanic or Latino participants. 0%

(B) 6% Black or African American, 9% Asian, and 100% Hispanic or Latino participants. SEE MORE

Planning For Success

- Inclusive Research Design
- Feasibility assessment
- Budgeting
- ENGAGE before recruiting
- Clear recruitment AND retention goals
- plan and track



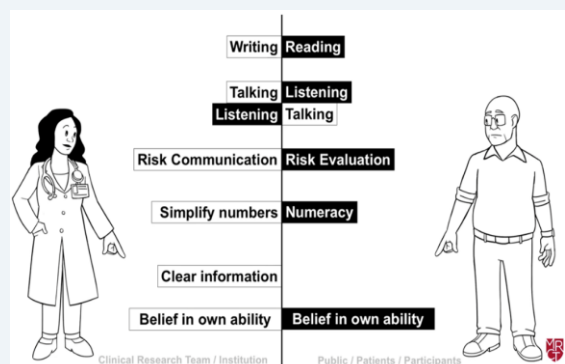
Building Trust in Research/Researchers

- Community-engaged research builds trust in research and researchers
- Based on building relationships to maintain trust instead of facilitating transactions
- Considers the significance of what the community wants for their lives and communities
- Creates mutual understandings that benefit everyone involved
- Reaching and involving the community to build trust
- Community advisory boards
- Town halls

Health Literacy



<https://mrccenter.org/health-literacy%E2%80%8B>



Health Literacy

RECRUITMENT MATERIALS	RECRUITMENT SCREENING	INFORMED CONSENT	DURING THE STUDY	STUDY RESULTS
Building relationships and sharing general research information with the community in an understandable way	Creating thoughtful study-specific recruitment materials and processes	Providing detailed study information to support informed decision making	Applying tools to support ongoing study participation	Sharing end of study communications and information

Designing Materials

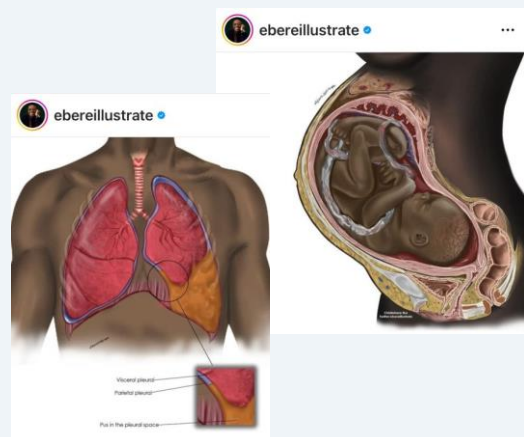
Be inclusive, minimize participant burden

Inclusivity
Cultural Sensitivity
Health Literacy
Accessibility

What questions are you asking?

How are you asking?

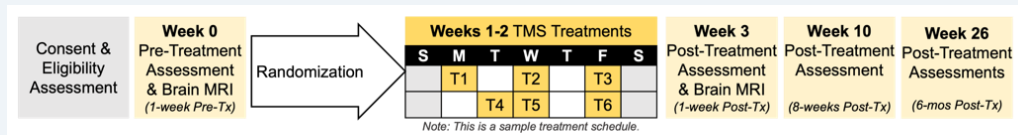
- Format
- Accessibility
- [REDCap branching logic](#)



Consent Considerations

[Improving Informed Consent with Minority Participants](#)

use of graphics in ICF



[Use of Electronic Informed Consent \(eIC\)](#)

[Hyperlinks](#)

[Short video](#)

[PowerPoint Presentation or flip chart](#)

Consent of Non-English speaking participants

[Budgeting considerations](#)

[Long Form translation](#)

[Short Form Consent](#)

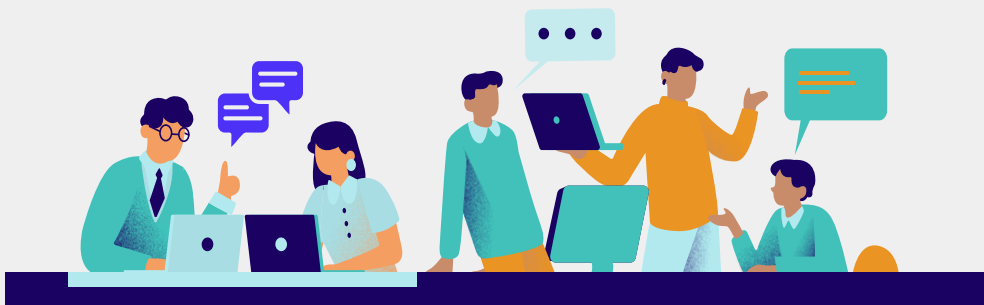
Cultural Sensitivity: Representation Matters

- Culturally sensitive research is person-centered
- Culture and language are diverse and continually evolving
- People may not identify as you see them

Implementation: An Ongoing Effort

- Involve family members and caregivers in recruitment efforts and study visits
- Be transparent about risks and benefits of research participation
- Revisit study plans, understand barriers to participation, and discuss novel strategies
- Disseminate research findings with the community and stakeholders

BREAKOUT SESSION



Discussion Questions for Breakout Session

1. What is the importance of including this special population in research?
2. How would you reach and involve this special population in the research before, during, and after the study?
3. What are the benefits and barriers to research participation for this special population?



FINAL THOUGHTS



Study Design Barriers to Minority Participation

BARRIERS

Mistrust

- Understanding the Value
- Fear
- Stigma of participating
- Communications style from investigator/staff

Lack of comfort with the process

- Mistrust of Process
- Fear
- Family Members opinions
- Information

Lack of Information

- Fear
- Stigma of participating

Time and Resource Constraints

- Financial Burden
- Time Commitment
- Transportation
- Compensation and logistics

Lack of Awareness

- Understanding the Value
- Information

COMMUNICATION TO PATIENTS

- Number one priority is your health and safety
- Extensive research and testing
- Many people have received the medication
- Your health will be closely monitored
- Potentially improving your own health

- Have a clear understanding
- Give you info for an informed decision
- Participation is voluntary
- Appreciate your taking part in study
- Investigator and coordinator main contacts
- Closely monitor your health
- Attend to potential side effects
- Track your progress
- Answer Questions
- Close Relationship with PCP

- Get you info you need for informed decision
- Provide patient information
- Give complete answers
- Direct you to someone who can answer questions
- Info you need to feel in control
- Answer questions you didn't think to ask
- Think about every aspect of participation
- You're not doing this alone
- Answer questions at every step
- Can always sit down and chat

- Thank you for considering
- Doctor can monitor your health and safety

Increasing clinical trial awareness is of lowest priority to potential patients – no items

THEMES

- Reinforce personal health
- Ensure Safety

- Confirm clear information is provided for decision-making
- Appreciate involvement
- Reinforce personal health
- Ensure safety

- Confirm clear information is provided for decision-making
- Emphasize available support

- Make trials more patient centric
- Provide transportation, flexible hours, compensation
- Create mobile app, proved cell phones

But important to properly set context – needs to precede other messages

Clark, L. T., et al. (2019).

QUESTIONS?



Tangible Takeaways

MRCT has a [program devoted to DEI](#) as well as several [case studies](#) available for review and a number of [webinars](#) on this topic

[MRCT Center: Accessibility by Design \(AbD\) Toolkit](#)

[The Three C's for Creating a Culture of Inclusion](#)

[Coursera Recruiting for Diversity and Inclusion Specialization](#)

[Coursera Faster Together, Enhancing the Recruitment of Marginalized Communities in Clinical Trials](#)

[FDA Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials](#)

[Community Engagement Toolkit](#)

[More Information on Health Literacy](#) and [another](#)

[Unconscious Bias Resources for Health Professionals](#)

[UVM 2023 Health Equity Summit – “Closing the Margin: Avenues to Health Equity”](#) – open to all

Tangible Takeaways (continued)

Informed Consent:

[Improving Informed Consent in Minorities](#)

[HHS Guidance on Electronic Informed Consent \(eIC\)](#)

Excellent OHRP series on [Research Participant Payments](#)

[Use of Electronic Informed Consent \(eIC\)](#)

- [Long Form translation](#)
- [Short Form Consent](#)

[Phenx Toolkit](#) - provides standard data collection measures for designing questionnaires

[Demographics](#),

[SDOH Collection](#)

[Importance of Sexual Orientation and Gender Identity \(SOGI\) Data Collection](#)

[NIH Guidance on collecting race, ethnicity, gender, sexuality](#)

[Branching Logic in REDCap – How to Guide](#)

Areas to Look for Population Data:

[CDC Data and Statistics](#) (split up by topic)

[U.S. Census Bureau QuickFacts](#)

[Area Deprivation Index](#)

Also: Local Health Department databases, Community Health Needs Assessments, Community Health Improvement Plans

THANK YOU!

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