

Workshop on Inclusive Participation in Clinical Research

March 30 – 31, 2023

National Institute on Minority Health and Health Disparities (NIMHD)
Zoom Meeting

Meeting Objectives

The purpose of this workshop is to improve implementation of evidence-based best practices for inclusive participation in clinical research. This workshop will discuss evidence-based best practices to increase inclusive participation in clinical research, how to implement these practices, challenges to overcome, and lessons learned. Workshop topics are organized by stage in the research process: before the study, during the study, and after the study. Day two will include a special session that will feature representatives from the different entities involved in supporting and conducting clinical research (academia, pharma, community-based organizations, and federal agencies).

NIH Planning Committee

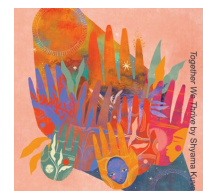
Gina Roussos, PhD [NIMHD], Co-Chair
Vanessa Marshall, PhD, CCRP [NIMHD], Co-Chair
Jennifer Alvidrez, PhD [ODP, OD, NIH]
Dawn Corbett, MPH [NIH]
Deborah Jaffe, PhD [NCI]

Olufunmilola (Lola) Olufemi, PhD [NINDS]
Nicole Redmond, MD, PhD, MPH [NHLBI]
Katrina Serrano, PhD [NIDDK]
Debbie Vitalis, PhD, MPH [NHLBI]

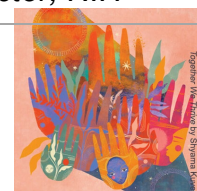
DAY 1 – THURSDAY, MARCH 30

All times listed are Eastern Daylight (UTC -4)

11:00 AM – 11:05 AM	Welcome and Meeting Overview <i>Gina Roussos, PhD, NIMHD</i> <i>Vanessa Marshall, PhD, CCRP, NIMHD</i>
11:05 AM – 11:15 AM	Opening Remarks <i>Eliseo J. Pérez-Stable, MD, NIMHD</i>
11:15 AM – 11:30 AM	Moving Beyond Inclusion to Intentional Integration to Drive Innovation, Rigor, and Equity <i>Monica Webb Hooper, PhD, NIMHD</i> <i>Janine Clayton, MD, FARVO, Office of Research on Women's Health, Office of the Director, NIH</i>



11:30 AM – 12:00 PM	<p>Cancer Control in the 21st Century Observations on Disparities in Health and Clinical Trials <i>Otis Brawley, MD, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University</i></p> <p><i>Colonel Jimmie Slade, Community Ministry of Prince George's County & Slade Enterprises Consulting</i></p>
12:00 PM – 12:10 PM	<p>Discussion/Q&A <i>Moderators: Gina Roussos, PhD, NIMHD</i> <i>Vanessa Marshall, PhD, CCRP, NIMHD</i></p>
12:10 PM – 12:20 PM	Break
<p>Session 1: Before the Study</p> <p><i>This session covers the planning and preparation that occurs before launching a study, including making recruitment plans, choosing a study site and research team members, and engaging with the community. Part 1 will focus on specific initiatives to address pre-study processes that impact diversity in clinical research. Part 2 will focus on specific aspects of the pre-study process.</i></p>	
<p>Part 1: Specific Initiatives <i>Moderator: Yewande Oladeinde, PhD, NIMHD</i> <i>Co-Moderator: Dawn Corbett, MPH, Office of the Director, NIH</i></p>	
12:20 PM – 12:35 PM	<p>The All of Us Research Program: Making Precision Medicine a Reality for All <i>Martin Mendoza, PhD, All of Us Research Program, Office of the Director, NIH</i></p>
12:35 PM – 12:50 PM	<p>FDA Efforts to Advance Racial and Ethnic Minority Participation in Clinical Trials <i>RDML Richardae Araojo, PharmD, MS, Office of Minority Health and Health Equity, Office of the Commissioner, U.S. Food and Drug Administration</i></p>
12:50 PM – 1:05 PM	<p>Role of the Research Institution: Clinical Trials Transformation Initiative Diversity Project <i>Luther T Clark, MD, FACC, FACP, Patient Innovation & Engagement, Global Medical and Scientific Affairs, Merck</i></p>
1:05 PM – 1:20 PM	<p>Action and Accountability: Equity by Design <i>Willyanne DeCormier Plosky, DrPH, Multi-Regional Clinical Trials (MRCT) Center, Brigham and Women's Hospital</i></p>
1:20 PM – 1:40 PM	<p>Discussion/Q&A <i>Moderator: Yewande Oladeinde, PhD, NIMHD</i> <i>Co-Moderator: Dawn Corbett, MPH, Office of the Director, NIH</i></p>



1:40 PM – 2:00 PM	Break
Part 2: Specific Topics <i>Moderator: Jennifer Alvidrez, PhD, Office of Disease Prevention (ODP), Office of the Director, NIH</i> <i>Co-Moderator: Debbie Vitalis, PhD, MPH, National Heart, Lung, and Blood Institute (NHLBI)</i>	
2:00 PM – 2:15 PM	Community Outreach and Engagement: Paving the Way to Meaningful Research Relationships with Communities <i>Marvella Ford, PhD, MSW, MS, Medical University of South Carolina Hollings Cancer Center</i>
2:15 PM – 2:30 PM	Strategies Toward Social Justice: Inclusive Participation in the Clinical Research Enterprise <i>Bernadette Boden-Albala, PhD, University of California Irvine Public Health</i>
2:30 PM – 2:45 PM	Determining an Appropriate Study Population: Challenges in Policy and Practice <i>Nicole Redmond, MD, PhD, MPH, NHLBI</i>
2:45 PM – 3:05 PM	Discussion/Q&A <i>Moderator: Jennifer Alvidrez, PhD, ODP, Office of the Director, NIH</i> <i>Co-Moderator: Debbie Vitalis, PhD, MPH, NHLBI</i>
3:05 PM – 3:10 PM	Break
<p>Session 2: During the Study <i>Moderator: Debbie Vitalis, PhD, MPH, NHLBI</i> <i>Co-Moderator: Rebecca Favor, DrPH, CPH, Office of Director, NIH</i></p> <p><i>This session covers the steps involved in conducting a clinical research study, starting with participant recruitment, and ending with the final round of data collection and any follow-up procedures.</i></p>	
3:10 PM – 3:25 PM	Payment for Research Participation: Takeaways from OHRP's 2022 Exploratory Workshop <i>Natalie Klein, PhD, Office of Human Research Protections, U.S. Department of Health and Human Services</i>
3:25 PM – 3:40 PM	Community-Engaged Approaches for Equitable Representation in Research <i>Namratha R. Kandula, MD, MPH, Northwestern University Feinberg School of Medicine</i>
3:40 PM – 3:55 PM	Developing Trust: Engaging Referring Physicians as Partners in Health Care Research <i>Arch G. "Chip" Mainous III, PhD, College of Public Health and Health Professions, University of Florida</i>



3:55 PM – 4:15 PM	Discussion/Q&A <i>Moderator: Debbie Vitalis, PhD, MPH, NHLBI</i> <i>Co-Moderator: Rebecca Favor, DrPh, CPH, Office of Director, NIH</i>
Closing Remarks and Networking Session	
4:15 PM – 4:25 PM	NIDCD’s Efforts to Enhance Inclusive Participation in Clinical Research <i>Debara Tucci, MD, MS, MBA, National Institute on Deafness and Other Communication Disorders (NIDCD)</i>
4:25 PM – 4:30 PM	Closing Remarks: What to Look Forward to for Day 2 <i>Gina Roussos, PhD, NIMHD</i> <i>Vanessa Marshall, PhD, CCRP, NIMHD</i>
4:30 PM – 5:00 PM	Networking <i>Registered attendees are placed in Zoom breakout rooms. A list of suggested topics will be provided to guide discussion.</i>
5:00 PM	Adjourn

DAY 2 – FRIDAY, MARCH 31	
<i>All times listed are Eastern Daylight (UTC -4)</i>	
11:00 AM – 11:05 AM	Welcome and Day 2 Overview <i>Gina Roussos, PhD, NIMHD</i> <i>Vanessa Marshall, PhD, CCRP, NIMHD</i>
Session 3: After the Study <i>Moderator: Katrina Serrano, PhD, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)</i> <i>Co-Moderator: Jarrett Johnson, DrPH, MS, NIMHD</i> <i>This session covers the activities that take place after data collection is completed, including data analysis and interpretation; communication of study findings via reports, peer-reviewed publications, and other forms of media; and translation of study findings into clinical practice.</i>	
11:05 AM – 11:20 AM	Improving Representation in Clinical Trials and Research - the 2022 National Academies Report <i>Kirsten Bibbins-Domingo, PhD, MD, MAS, University of California San Francisco School of Medicine</i>



11:20 AM – 11:35 AM	The Importance of Clinical Trials in Achieving Healthy Equity <i>Mona Fouad, MD, MPH, University of Alabama-Birmingham School of Medicine</i>
11:35 AM – 11:50 AM	Study Evaluation With Focus on Diversity and Inclusion Metrics <i>Leonard E. Egede, MD, MS, Medical College of Wisconsin</i>
11:50 AM – 12:10 PM	Discussion/Q&A <i>Moderator: Katrina Serrano, PhD, NIDDK</i> <i>Co-Moderator: Jarrett Johnson, DrPH, MS, NIMHD</i>
12:10 PM – 12:15 PM	Break

Session 4: Special Populations Panel Discussions

These moderated panel discussions will cover best practices for conducting clinical research with populations requiring special considerations, such as children, older adults, and pregnant and lactating persons. During the first half of each panel, the moderator will ask questions that the panelists received in advance. During the second half of each panel, the panelists will answer questions from the audience.

Panel Discussion 1: Racial and Ethnic Minority Populations

Moderator: Olufunmilola (Lola) Olufemi, PhD, National Institute of Neurological Disorders and Stroke

Co-Moderator: Jennifer Alvidrez, PhD, ODP, Office of the Director, NIH

12:15 PM – 12:55 PM	<p>American Indian and Alaska Native Populations <i>Denise A. Dillard, PhD, Southcentral Foundation and Washington State University</i></p> <p>Black/African American Populations <i>Lucile Adams-Campbell, PhD, Georgetown University Lombardi Comprehensive Cancer Center</i></p> <p>Hispanic/Latino Populations <i>Greg Talavera, MD, MPH, San Diego State University College of Sciences</i></p> <p>Native Hawaiian and Pacific Islander Populations <i>Vaatausili “Va’a” Tofaeono, MBA, American Samoa Community Cancer Coalition</i></p> <p>Asian American Populations <i>May Sudhinaraset, PhD, UCLA Fielding School of Public Health</i></p>
12:55 PM – 1:00 PM	Break



Panel Discussion 2: Special Consent Considerations

Moderator: Sonia Arteaga, PhD, Environmental Influences on Child Health Outcomes (ECHO) Program, Office of the Director, NIH

Co-Moderator: Katrina Serrano, PhD, NIDDK

1:00 PM – 1:35 PM

Children

Hengameh Heidarian-Raissy, PharmD, University of New Mexico School of Medicine

Older Adults

Carrie Nieman, MD, MPH, Johns Hopkins University School of Medicine

Persons Who Are Incarcerated

Emily Wang, MD, MAS, Yale University School of Medicine

Persons With Limited English Proficiency

Tung Nguyen, MD, University of California San Francisco School of Medicine

Panel Discussion 3: Special Populations

Moderator: Martin Mendoza, PhD, All of Us Research Program, Office of the Director, NIH

Co-Moderator: Debbie Vitalis, PhD, MPH, NHLBI

1:35 PM – 2:15 PM

Sexual and Gender Minority Populations

Billy Caceres, PhD, RN, FAHA, FAAN, Columbia University School of Nursing

Pregnant and Lactating Persons

Sindhu K. Srinivas, MD, MSCE, Hospital of the University of Pennsylvania

Persons With Disabilities

Angel L. Miles, PhD, National Institute on Disability, Independent Living, and Rehabilitation Research, Administration for Community Living

Rural Populations

Gloria Coronado, PhD, Kaiser Permanente Center for Health Research

Socioeconomically Disadvantaged Populations

Kali Zhou, MD, MAS, Keck School of Medicine, University of Southern California

2:15 PM – 2:30 PM

Break



Session 5: Collaborator Perspectives Panel Discussion

In these moderated panel discussions, representatives from the different entities involved in supporting and conducting clinical research offer their perspectives on how to increase the participation of individuals from underrepresented populations. During the first half of each panel, the moderator will ask questions that the panelists received in advance. During the second half of each panel, the panelists will answer questions from the audience.

Panel Discussion 1: Community and Patient Perspectives

Moderator: Karriem Watson, All of Us Research Program, Office of the Director, NIH

Co-Moderator: Debbie Vitalis, PhD, MPH, NHLBI

2:30 PM – 3:05 PM

Community Organizations

Rev. Kendrick E. Curry, PhD, MS, Mdiv, Community Engagement Alliance (CEAL) Against COVID-19 Disparities Steering Committee and Pennsylvania Ave Baptist Church

Ricki Fairley, MBA, TOUCH, The Black Breast Cancer Alliance

Patient Advocacy Organizations

Shonta Chambers, MSW, Patient Advocate Foundation

Alissa Torres, MSW, Mental Health America

Panel Discussion 2: Funder, Regulatory, and Policy Perspectives

Moderator: Bob McNellis, MPA, PA, ODP, Office of the Director, NIH

Co-Moderator: Olga Herren, PhD, NIMHD

3:05 PM – 3:45 PM

Pharma

Brittany Gerald, BS, Moderna

Academia

Peter J. Embí, MD, MS, FACP, FACMI, FAMIA, FIAHSI, Vanderbilt University Medical Center

Federal Agencies

Robert Califf, MD, U.S. Food and Drug Administration

Non-Federal Funders

Nakela L. Cook, MD, MPH, Patient-Centered Outcomes Research Institute

Policy and Advocacy Organizations

Jenny Luray, MPA, Research!America

3:45 PM – 3:55 PM

Break

Session 6: Next Steps and Actionable Solutions for Inclusive Research

In this session, speakers, attendees, and moderators will engage in an interactive discussion about next steps and will identify potential actionable solutions for increasing inclusive participation in clinical research.



3:55 PM – 4:00 PM	<p>Overview of What We Learned During the Workshop <i>Gina Roussos, PhD, NIMHD</i> <i>Vanessa Marshall, PhD, CCRP, NIMHD</i></p>
4:00 PM – 4:40 PM	<p>Open Discussion: Next Steps and Actionable Solutions <i>Gina Roussos, PhD, NIMHD</i> <i>Vanessa Marshall, PhD, CCRP, NIMHD</i></p>
Closing Session	
4:40 PM – 4:50 PM	<p>Pulling It All Together – NIH Efforts in DEIA <i>Marie Bernard, MD, Office of the Chief Officer for Scientific Workforce Diversity, Office of the Director, NIH</i></p>
4:50 PM – 4:55 PM	<p>Thank You <i>Gina Roussos, PhD, NIMHD</i> <i>Vanessa Marshall, PhD, CCRP, NIMHD</i></p>
4:55 PM	Adjourn

