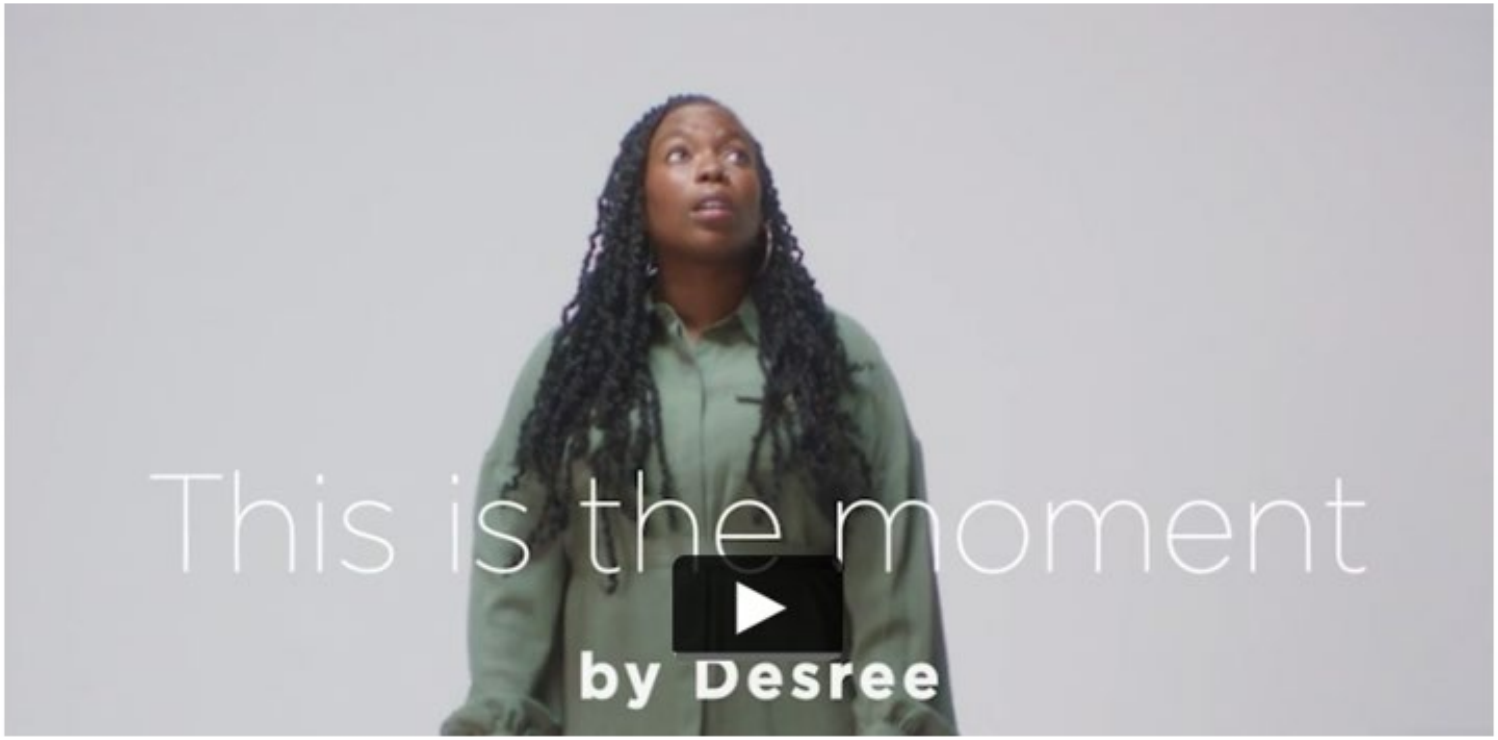
# FAIR Work group

INTRODUCTION BY AISHA GHORI OZAKI

PRESENTED BY EDETH ENGEL

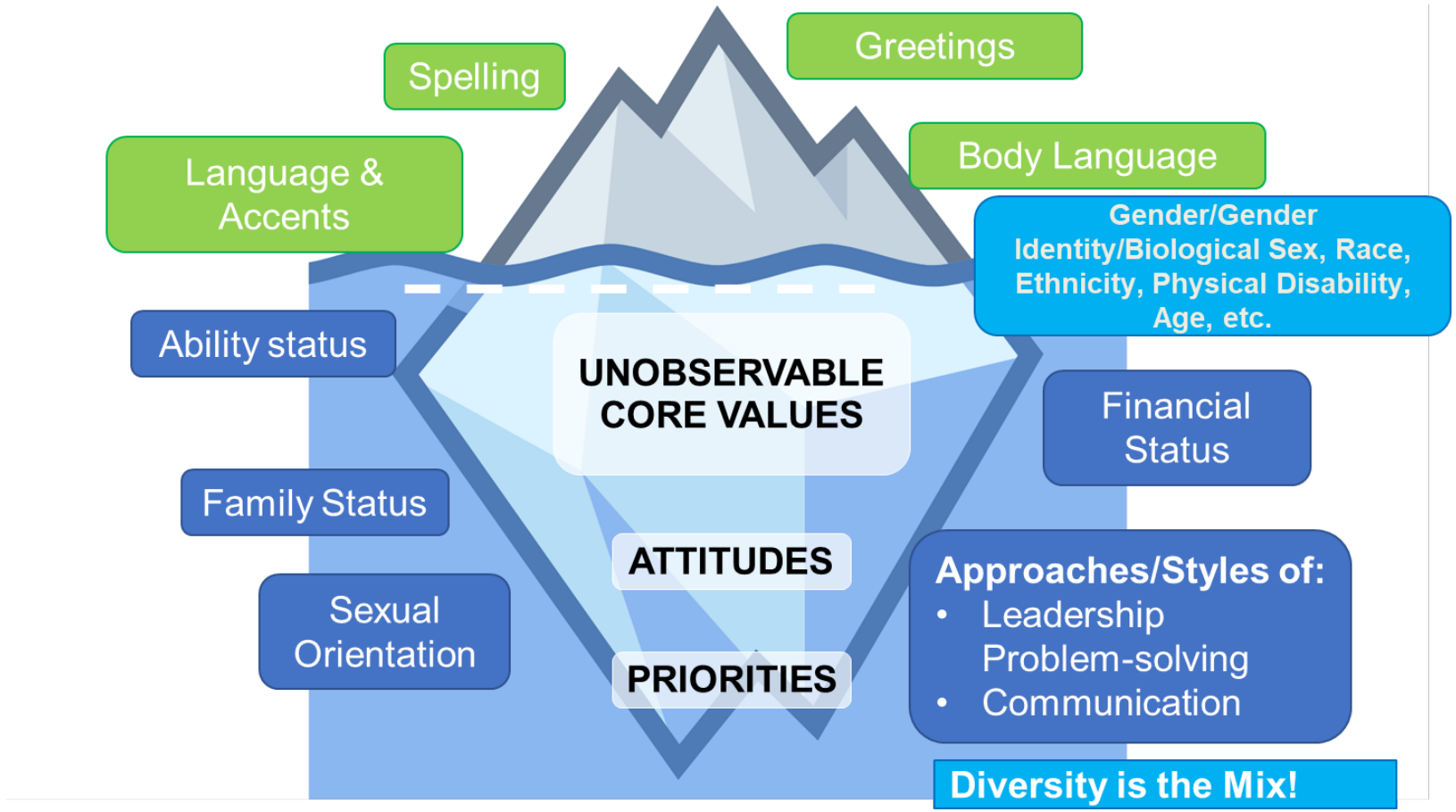

This is the moment
by Desree

- Office of Equity
- Office of Institutional Diversity & Inclusion
- Office for Research - Diversity, Equity & Inclusion+
  - Coaching, facilitation and consulting
  - Amplification of institutional resources
  - Learning experiences and events
  - Leading DEI course support and Next 250 Anti-racism workshop
  - Website
  - And so much more

# OR Values


In the Office for Research, we:
UNDERSTAND EMPATHY
We treat each other with compassion, dignity, and respect through listening to learn, not to confirm our views.
MODEL ACCOUNTABILITY
We keep our commitments, actively participate, and take ownership of our successes and failures.
ENSURE FAIRNESS
We build transparent and equitable processes, and embrace high ethical standards.
EMBRACE COMMUNITY
We build and nurture relationships between people and enable connections to grow, learn, and excel.
VALUE CREATIVITY
We take responsible risks and encourage autonomy to find innovative solutions and continuous improvement.

# What is diversity?



# Systemic understanding

# Moving towards belonging

**The intervention for othering is not same-ing, but belonging. Belonging is based on the recognition of our full humanity without having to become something different or pretend we're all the same. We are always both the same (humanity) and different (human), and are also multiple and dynamic, constantly renegotiating who we are. Belonging requires both agency and power to cocreate. But true belonging means we are not just creating for our group(s), but for all.**

***- john a. powell***

***Professor, UC-Berkeley Othering and Belonging Institute***

# FDA  Safety and Innovation Act (FDASIA)

- The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012, expands the FDA's authorities and strengthens the agency's ability to safeguard and advance public health.
- Section 907: Inclusion of Demographic Subgroups in Clinical Trials
  - This subsection recommends that medical product applications submitted for marketing approval improve their demographic subgroup data's completeness, quality, and availability.

# Section 907

- Sec. 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA) directed FDA to investigate how well demographic subgroups (sex, age, race and ethnicity) in applications for medical products – drugs, biologics and devices, submitted to the agency for marketing approval:
  - 1) Are included in clinical trials; and
  - 2) If subgroup-specific safety and effectiveness data are available.
- Under Section 907, the FDA was also to create an action report to deliver to Congress

# Section 907

- In 2014, the FDA published its final report and released the *Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data.*
- Findings indicated that age and sex were consistently reported and some subgroup safety information was available, however race and ethnicity were often not reported and largely not enough data was available for safety information.
- Focus areas included:
  - 1. Quality: to improve the completeness and quality of demographic subgroup data;
  - 2. Participation: to identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation; and
  - 3. Transparency: to improve the public availability of demographic subgroup data.

# POLL

Do your research studies typically gather information about patient demographics, specifically race?

# Labeling Recommendations

| Recommendation in FDA approved labeling | Example drug | Racial/ethnic information in the labeling | Rationale |
|---|---|---|---|
| Indicated for a specific racial population | Isosorbide dinitrate/ hydralazine | Indicated for self-identified blacks | Based on retrospective analyses, an effect on survival was reported in blacks, with little evidence to suggest an effect in the whites |
| Contraindicated in case of G6PD deficiency which is present in a higher frequency in specific racial populations | Rasburicase | Contraindicated in G6PD deficiency. Screen patients at a higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) prior to starting therapy | Recommendations to screen patients at a higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) prior to starting therapy because of the increased risk of hemolysis in patients with G6PD deficiency |
| Warnings and precautions directed at a specific racial population | Carbamazepine | Boxed warning for *HLA-B*1502* in Asian patients | Incidence of adverse event and prevalence of genetic factor are higher in Asian populations |
| Recommendations for considering alternative therapy for a specific racial population | ACE inhibitors or Angiotensin II antagonists, e.g., candesartan and losartan | A general statement for African-Americans/blacks in the labeling of a number of drugs belonging to this class because of the smaller effect size observed | Pathophysiologically, hypertension is driven less by the renin-angiotensin-aldosterone system in African-Americans/blacks |
| Different dosing recommendation for a specific racial population | Rosuvastatin | Lower initial starting dose in Asians | Based on clinical observation of ~2-fold higher exposure in Asians compared to Caucasians |
| | Tacrolimus | Higher dose in African-American transplant patients | Based on clinical observation; metabolized by CYP3A5 and African-American/black populations have low prevalence of reduced function variants compared to Caucasians |

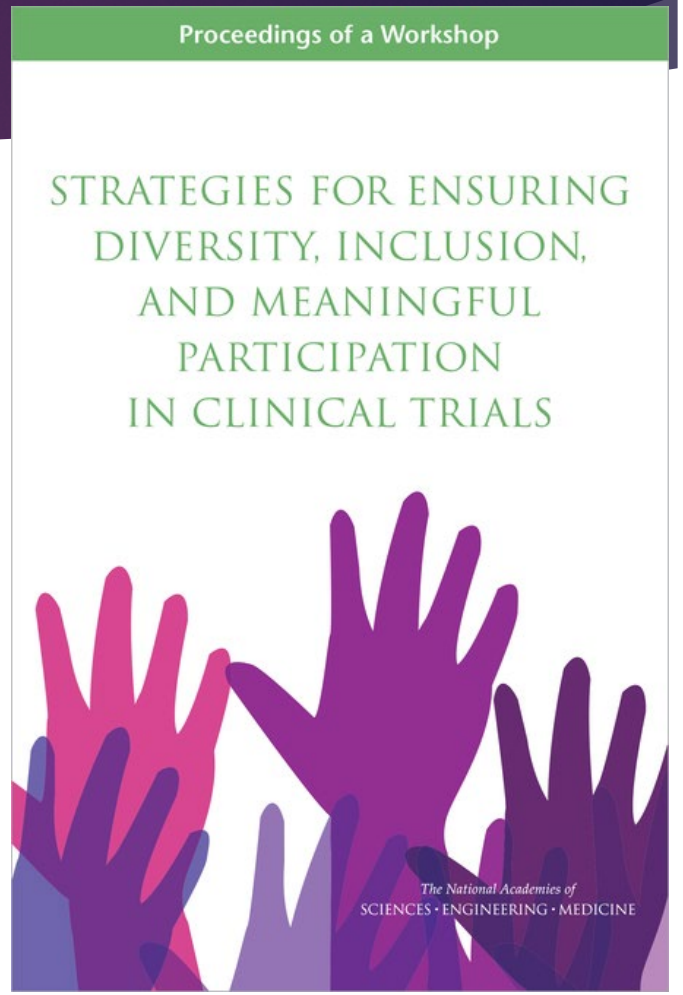
G6PD: glucose-6-phosphate dehydrogenase; HLA-B: human leukocyte antigen B; ACE: angiotensin-converting enzyme; CYP3A5: Cytochrome P450 3A5.

# Efforts FDA has taken

- FDA partnered with stakeholders including NIH and Office of Minority Health to expand efforts related to the Action Pan and included outreach to under-represented populations.
  - PSAs were created and translated along with blogs, newsletters, brochures, and videos
  - Medical product applications were revised to enhance information on demographic subgroups in medical product applications
  - Additional inclusion training for FDA staff
  - Guidance on Sex-specific data in medical device clinical studies was created
  - Increased monitoring and data collection on subgroup participation rates
  - Efforts to enhance appropriate use of enrollment criteria were put in place with guidance documents and thorough review (such as not limiting age ranges in populations affected by relevant diseases)
  - Improve product labeling as relevant to demographic data

# Office of Minority Health (OMH)

- The OMH is a subgroup under the FDA. They have put together a webinar (available as PDF) to outline current problems as well as actionable items.



# OMH Key Points

- Barriers to participation in clinical trials include mistrust, costs, language and cultural differences, lack of awareness of trials, and trial designs that tend to exclude certain subgroups.
- Despite these barriers, when given the opportunity, these subgroups are just as likely to participate in clinical trials as the majority population.
- The foundation of participation in a clinical trials is trust, whether in a health care provider, a research, a funder, or a government.
- Engaging communities not as subjects but as partners in research can not only increase participation but change the nature of clinical trials.
- Diverse representation among research leaders and research teams can boost the participation of underrepresented groups in clinical trials.
- New technologies, such as apps on smartphones could help explain clinical trials more simply and clearly and improve recruitment into trials.

# NIH Inclusion Policies

- All NIH-funded studies that meet the NIH definition for clinical research must address plans for the inclusion of women and people of color within the application or proposal as well as pregnant persons "in all circumstances in which their inclusion is scientifically valid and ethically permissible".
- Annual report must cover the breakdown of sub-groups.
- The Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of marginalized groups as subjects in projects of clinical research.

# POLL

Do your studies typically include specific efforts to recruit a diverse and representative pool of participants?

# FAIR

- **F**ostering
- **A**ccessibility and
- **I**nclusivity in
- **R**esearch

# Workgroup Members

- Shannon Bowers
- Edeth Engel (co-Chair)
- Monica Kane
- Kimberly Rowan
- Lucas Sikorski (co-Chair)
- Nathalia Henry-Whitely
- Pranjal Patankar

# Mission and Vision Statement

- Our mission is to nurture inclusive and equitable practices across the Northwestern University human research landscape in alignment with the Belmont Principle of Justice.
- We will achieve this by partnering with groups across the University's human research protection program to create and share resources in order to implement these practices.

# HHS 45.CFR.46.111(3)

- (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

# Center for Community Health (CCH)

- FAIR met with Dr. Darius Tandon to discuss collaboration of the two departments' efforts.
- Together we have created guidance for IRB templates on how study teams can best include stakeholder engagement in IRB protocols.
- Guidance will also direct study teams to work with CCH so that available resources can be utilized.

# New Protocol Language

- Your recruitment plan should incorporate methods that specifically address and detail how potential participants from minority/under-represented populations (with respect to the study) will be recruited. This is to ensure that the recruitment plan is inclusive and representative of the eligible population within the Chicagoland area and considers the impact of the research on all such populations.

# POLL

Which of these barriers present the greatest challenge to recruitment?

- Cost
- Limited to narrow NU patient population (convenience)
- Study team members do not have access or experience in reaching populations outside of NU
- Language
- Other

# Ongoing Initiatives

- Non-English Speakers: shift in expectations regarding inclusion/exclusion of non-English speakers, more effort is expected to include non-English speakers. The IRB Office will review your study-specific justification for the exclusion of non-English speakers as appropriate
- IRB is working on creating Spanish language consent form templates to promote inclusion.
- Promote the use of gender-inclusive language within demographics forms, consent forms, and recruitment material as applicable.
- Promote the sharing of study results with the participating communities to increase trust in research.

# Exploring future possibilities: Brainstorming topics

- **Research Community:** Include in protocol qualification section "how does the makeup of the study team improve accessibility of research to intended populations".
- **IRB Office:** Assess current IRB panel membership demographics.
- **Participants:** Devise plans for payment for parking by updating protocol template instructions to ask study teams to consider paying for transport/parking.

- **NU Community:** what does our community look like? What are the demographics of our Chicago-land and NU population? How does this inform recruitment plans?

# IRB Website Updates

- We have created a new website as a resource for Northwestern University Researchers
- https://irb.northwestern.edu/about/fair/index.html

# Fostering Accessibility and Inclusivity in Research (FAIR)

Our mission is to nurture inclusive and equitable practices across the Northwestern University human research landscape in alignment with the Belmont Principle of Justice. We will achieve this by partnering with groups across the University's human research protection program to create and share resources in order to implement these practices.

# Discussion

- What does DEI mean to you?
  - Go to menti.com and enter 5313 3686

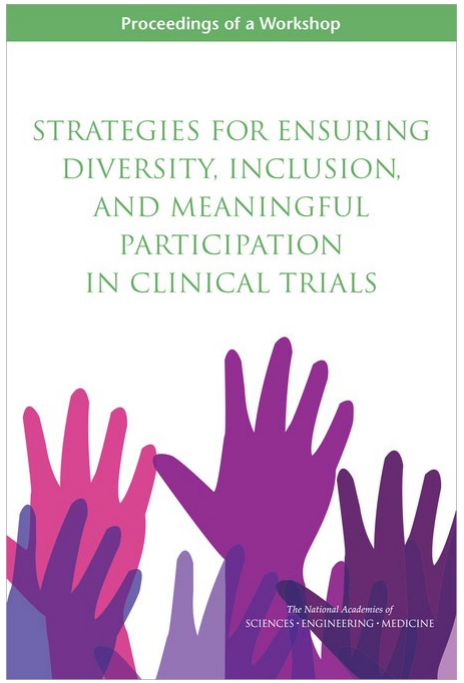
# Reflection

- How have you leveraged DEI+ in your research?

  Go to menti.com and enter 5313 3686

# Resources


- National Academies of Sciences, Engineering, and Medicine. 2016. *Strategies for Ensuring Diversity, Inclusion, and Meaningful Participation in Clinical Trials: Proceedings of a Workshop*. Washington, DC: The National Academies Press.https://doi.org/10.17226/23530.
- FDA. FDA action plan to enhance the collection and availability of demographic subgroup data. Silver Spring, MD: FDA, 2014.
- FDASIA Section 907: Inclusion of Demographic Subgroups in Clinical Trials. Food and Drug Administration Web site. https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fdasia-section-907-inclusion-demographic-subgroups-clinical-trials. Accessed October 18, 2021.
- Public Health Service Act Section 492B, 42 U.S.C. Section 289a-2,

# For Group Discussion

We're interested in getting the perspective of other stakeholders about what else can be implemented, what is practical, what isn't, what are the barriers?

Any suggestions about how we can help researchers think about these issues when developing the protocols?

How can we be mindful of inclusion and accessibility as we review recruitment plans?

# For Group Discussion

What can the IRB Office do to support researchers in these efforts?

What institutional resources would be helpful to unfunded/investigator-initiated studies?

What are some examples of successful recruitment strategies and outreach that have resulted in diverse and representative participation?