

# NIMHD Perspectives on Minority Inclusion in Health Research

---

**NATHAN STINSON, JR., MD, PHD, MPH**

**DIVISION OF COMMUNITY HEALTH AND POPULATION  
SCIENCE**



# NIH Inclusion Policies

---

## NIH Revitalization Act of 1992, Public Law PL 103-43

- Women and Minorities **must** be included (unless justified) in
  - All clinical research studies
  - Phase III clinical trials, designed to permit valid analysis
- Cost is **NOT** allowed as an acceptable reason for exclusion
- NIH to support outreach efforts to recruit and retain women and minorities in clinical studies

## New Human Subjects and Clinical Trials Information Form

- Expanded sections on recruitment and retention of participants
- Increased reporting requirements for clinical trials



# NIH Inclusion Data by RCDC Category

## <https://report.nih.gov/RISR/#/>

NIH RCDC Inclusion Statistics Report

This report displays the typical representation of participants in human subject studies enrolled in FY2018 projects associated with the listed research, condition, or disease category. Median percent participation is presented for each demographic variable.

Adjust the filters to view characteristics by race or ethnicity or to exclude single population studies. Drill down to explore more detailed statistics.

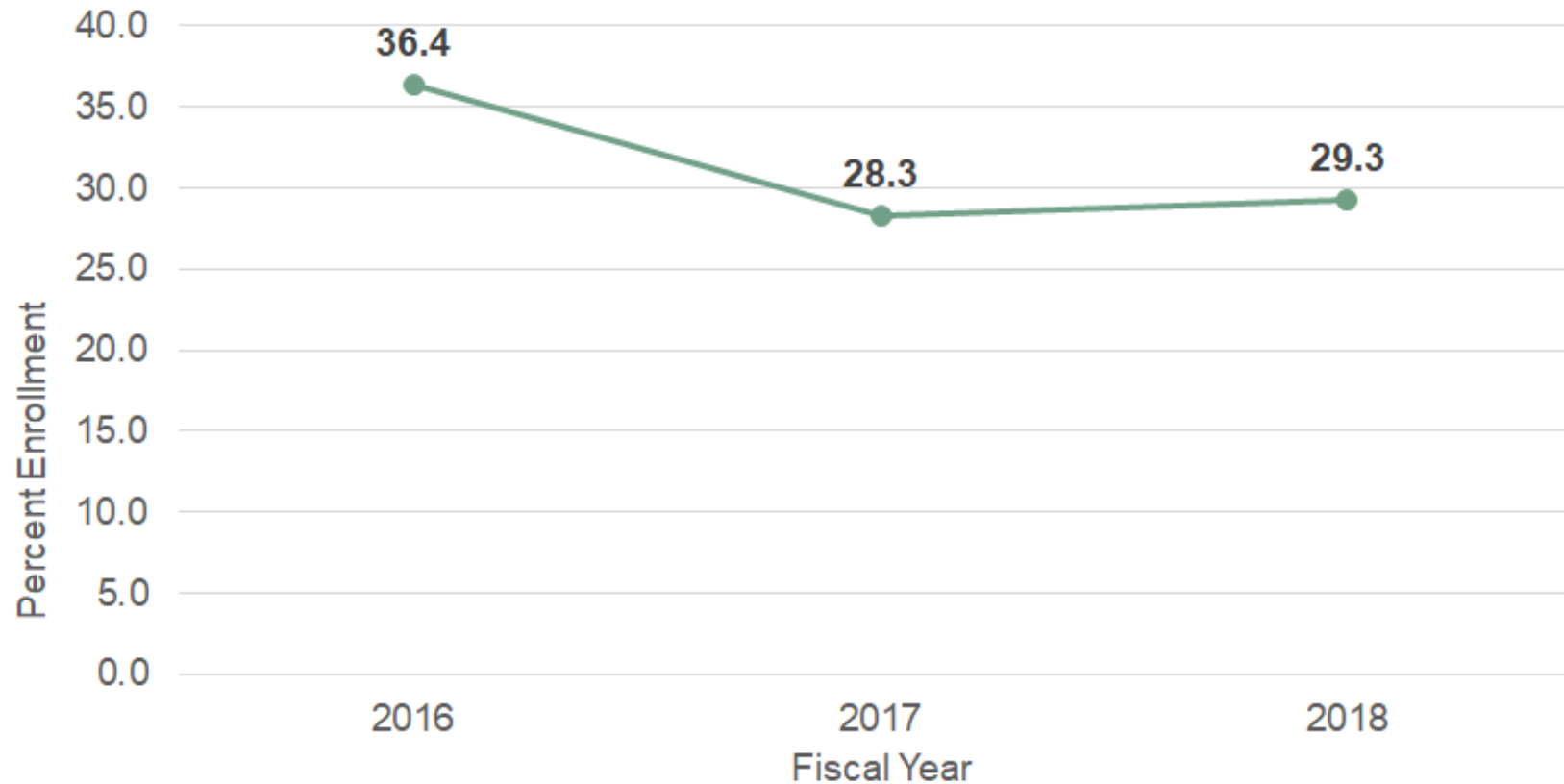
**\*\*Notes:** Research, condition, and disease categories are not mutually exclusive, so the same projects may appear in more than one category. All participants enrolled in a project's studies are included in all categories associated with that project. Individual research projects can be included in multiple categories so amounts depicted within each column of this table do not add up to the total participants enrolled in NIH-funded research.

**Example:** R01 IC12345 enrolled 300 participants and is associated with the Basic Behavioral and Social Science and Prevention categories. All 300 participants will appear in both the Basic Behavioral and Social Science and Prevention category totals for that IC.

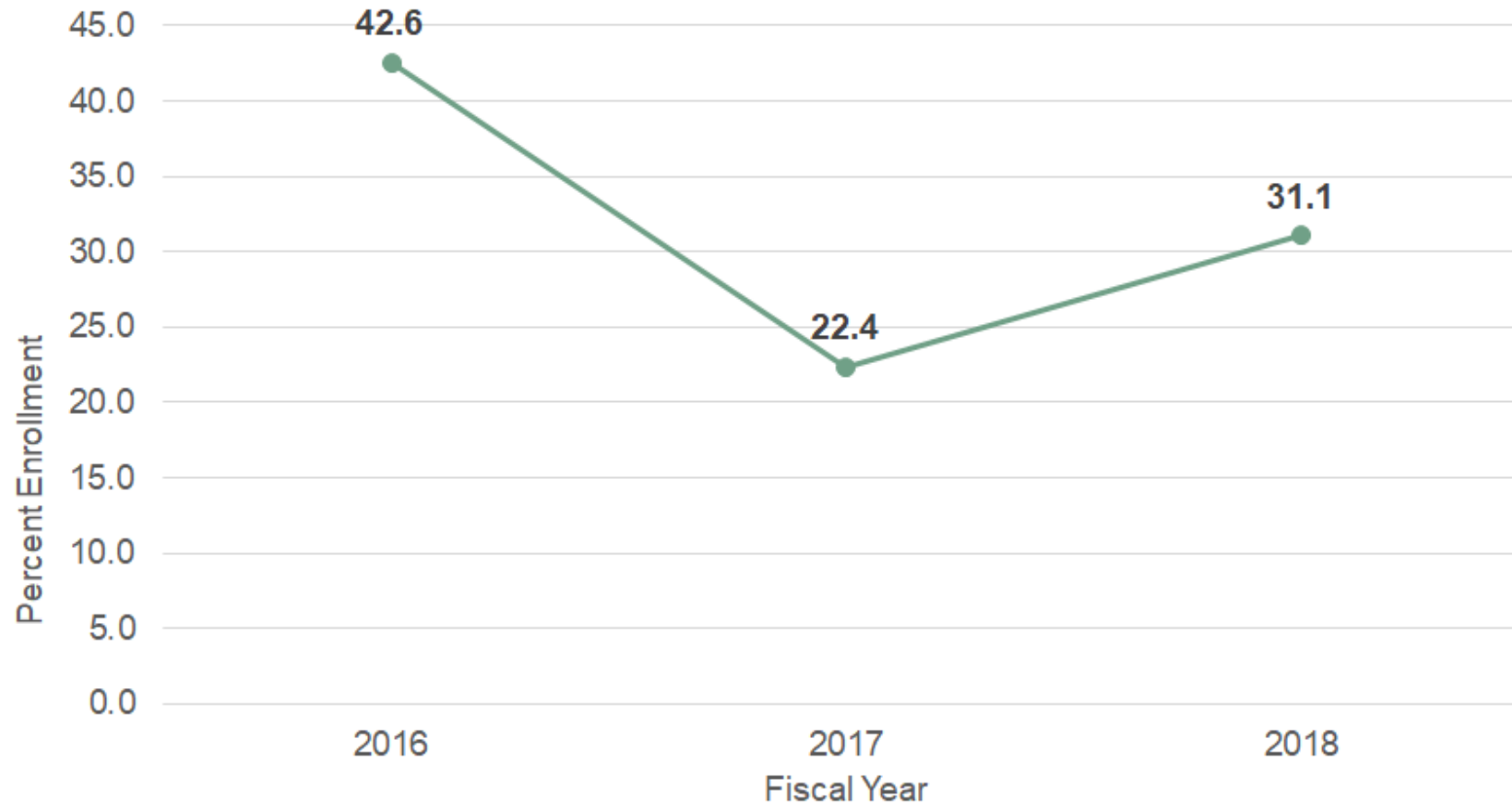
RCDC Category	Median % American Indian or Alaska Native Participants	Median % Asian Participants	Median % Native Hawaiian or Other Pacific Islander Participants	Median % Black or African American Participants	Median % White Participants	Median % Participants of More than One Race
ALS	<1%	<1%	<1%	2%	91%	<1%
Acquired Cognitive Impairment	<1%	<1%	<1%	7%	80%	<1%
Acute Respiratory Distress Syndrome	<1%	3%	<1%	16%	69%	<1%
Adolescent Sexual Activity	<1%	<1%	<1%	33%	31%	5%
Agent Orange & Dioxin	<1%	<1%	<1%	<1%	100%	<1%
Aging	<1%	<1%	<1%	9%	76%	<1%
Alcoholism, Alcohol Use and Health	<1%	<1%	<1%	12%	63%	2%
Allergic Rhinitis (Hay Fever)	<1%	2%	<1%	4%	78%	<1%
Alzheimer's Disease	<1%	<1%	<1%	6%	81%	<1%
Alzheimer's Disease Related Dementias (ADRD)	<1%	<1%	<1%	3%	81%	<1%
Alzheimer's Disease including Alzheimer's Disease Related Dementias (AD/ADRD)	<1%	<1%	<1%	6%	81%	<1%
American Indian or Alaska Native	8%	<1%	<1%	<1%	45%	<1%
Anorexia	<1%	10%	<1%	3%	77%	3%
Anthrax	<1%	<1%	<1%	7%	93%	<1%
Antimicrobial Resistance	<1%	<1%	<1%	15%	35%	<1%
Anxiety Disorders	<1%	2%	<1%	12%	67%	3%
Aphasia	<1%	2%	<1%	13%	74%	<1%
Arctic	100%	<1%	<1%	<1%	<1%	<1%



# NIH Racial and Ethnic Minority Enrollment in Clinical Research, US Sites FY2016 - FY2018



# NIH Racial and Ethnic Minority Enrollment, US Sites, NIH-Defined Phase 3 Studies FY2016-FY2018



# Interpreting Aggregate Enrollment

---

- Numbers for clinical research include secondary data analysis if dataset contains identifiers
- Mean percentages highly impacted by studies that include predominantly or entirely minorities
- Collapsing across health conditions elicits comparisons with US population, not according to the burden of disease for specific health conditions or numbers needed for valid subgroup analyses



# Expectations for NIMHD-funded Research

---

- Representation consistent with US population often not sufficient to address minority health/health disparities research questions
  - Consistent with disease risk or burden,
  - Stratified sampling to ensure adequate sample size for valid subgroup analysis, or
  - Reflective of the diversity of clinical and community intervention settings
- Inclusion important even if study will not be fully powered to conduct subgroup analysis for all groups



# Expectations for NIMHD-funded Research

---

- Meaningful inclusion of diverse populations
  - Appropriate inclusion of language minorities
  - Sampling and data collection strategies to minimize risks of confounding of race/ethnicity with SES, help-seeking, or other characteristics
  - Incorporation of relevant variables in order to interpret potential racial/ethnic differences in outcomes
- Attention to inclusion during conduct of research, not just in the application





# Expectations for NIMHD-funded Recruitment Research

---

- Beyond focus group studies about attitudes towards research
- Empirical testing of recruitment methods and strategies
  - Multi-level strategies that address investigator, research design, clinician, or health setting factors



# Ongoing Challenges in Achieving Greater Diversity in Clinical Research

---

- Absence of systematic corrective mechanisms
- Attention to inclusion left up to individual peer reviewers, NIH Institutes, Program Officials, journal editors
- Disincentives for having diverse samples
  - Acceptable to study a 'universal' phenomenon first before including minorities
  - Researchers may be penalized for inclusion without sufficient power for subgroup analysis
  - Still acceptable to exclude language minorities
- Prevailing belief that recruiting minorities is difficult



# NIH Community Engagement Alliance Against COVID-19 Disparities (CEAL)

---

**History:** Established in July 2020 as an NIH-wide effort to advance community-engaged research and outreach against COVID-19 in disproportionately impacted communities.

**Leadership:** Dr. Gary Gibbons, Director of NHLBI and Dr. Eliseo Pérez-Stable, Director of NIMHD to serve as co-leads for the effort.

**Charge:** Undertake an NIH-wide effort to:

1. Conduct urgent community-engaged research and outreach focused on COVID-19 awareness and education to address misinformation and mistrust; and
2. Promote and facilitate inclusion of diverse racial and ethnic populations in clinical trials (prevention, vaccine, therapeutics), reflective of the populations disproportionately affected by the pandemic.



# Thank you!

**Nathan Stinson, Jr.**  
**301-594-8704**  
**nathaniel.stinson@nih.gov**

