



Inclusive Participation in Clinical Research

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Diversity in Clinical Studies

- **To account for the diverse lived experiences and exposures of various populations, clinical studies need to be inclusive of populations to whom the results of the studies will apply**
- **Inclusion of women was the first issue with many studies only including men**
- **Inclusion of women and racial and ethnic minorities as defined by the Census were required to be collected and reported**
- **Reporting of Age at enrollment with inclusion of all ages required**
- **US or Foreign birthplace**



Inclusion of Women and Racial and Ethnic Minorities in NIH Research

- Women and members of racial and ethnic minority groups must be included in all NIH-funded clinical research studies
- **Any exclusions must be based on compelling rationale**
- Sex/gender and race/ethnicity analyses required for NIH-defined Phase 3 clinical trials

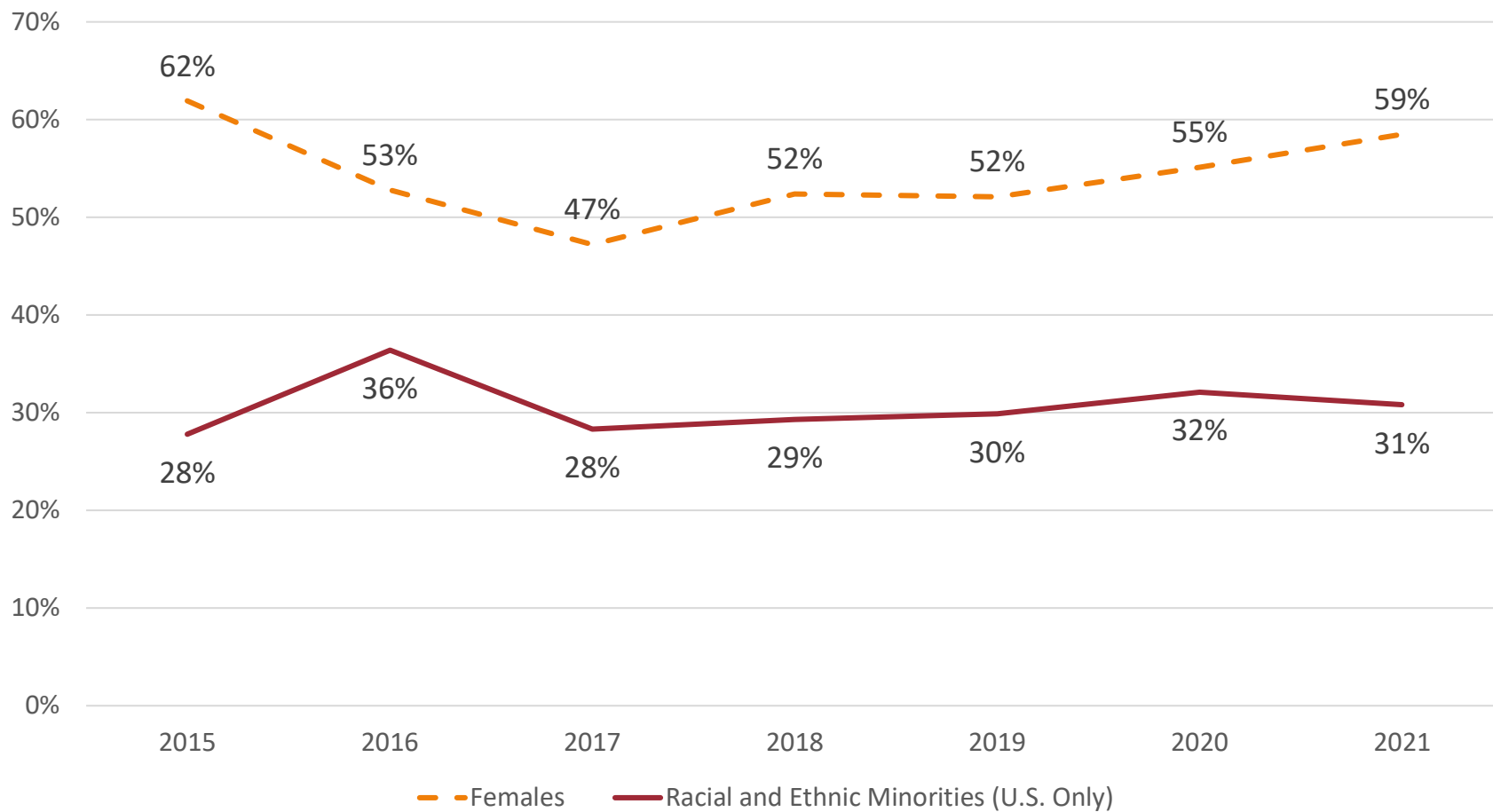


Current Status of Inclusive Participation in Clinical Research in FY 2022

- **51.5%** of participants are female
- **13%** African American, **12.1%** Latino, **3.4%** Asian, **1%** AI/AN, and **0.3%** Native Hawaiian/Pacific Islander
- 30% minoritized populations
- **12.2%** unknown — mostly due to EHR studies
 - Phase 3 Trials – only 8.2% are unknown
- Inclusion across the lifespan with emphasis for persons >80 yr. and children <2 yr.
- System to track inclusion by categories of disease



Inclusion in NIH Clinical Research FY 2016-2021

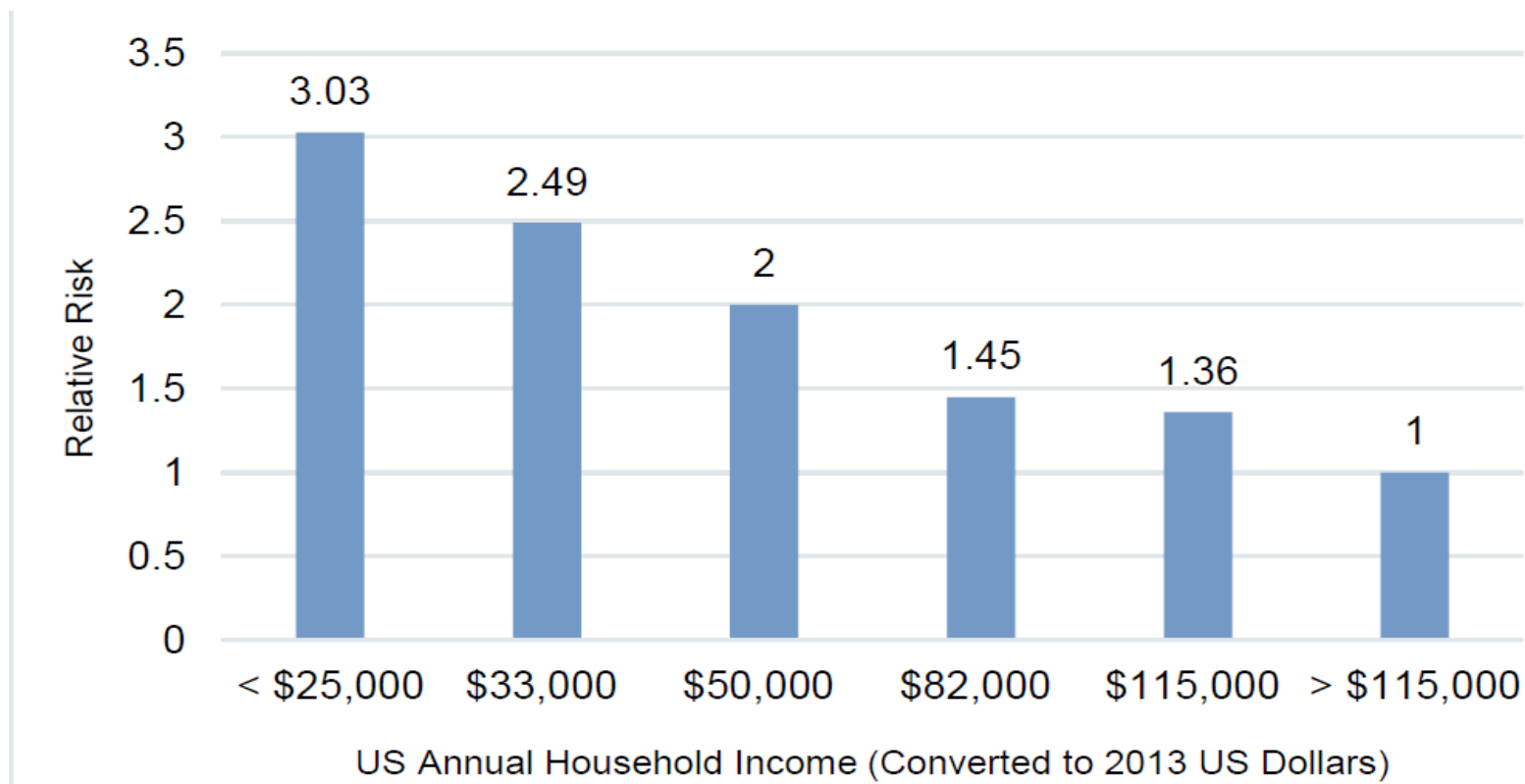


Populations with Health Disparities

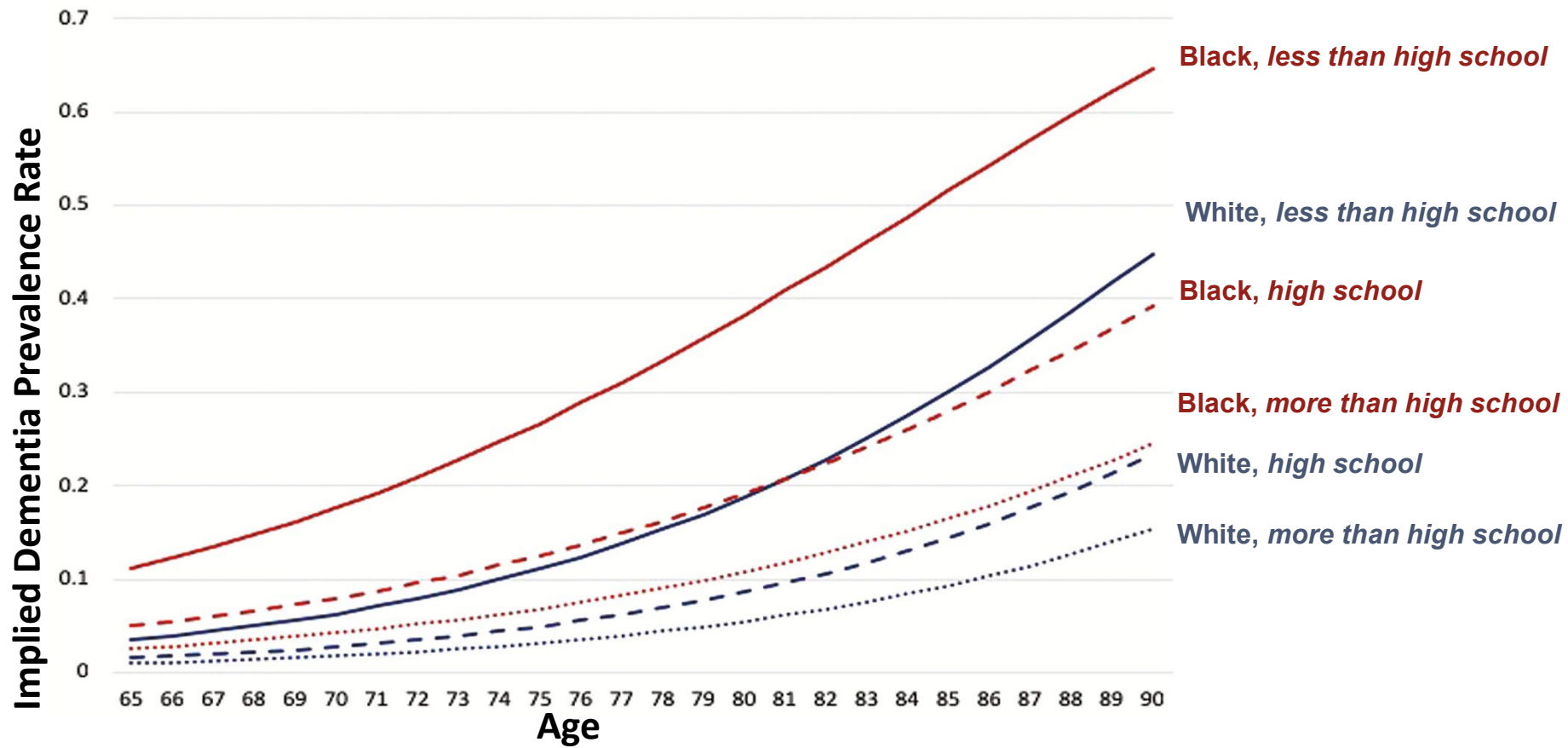
- Racial and ethnic minority populations in census
- Less privileged socio-economic status
- Underserved rural residents
- Sexual and gender minorities
- Social disadvantage that results in part from being subject to discrimination or racism, and being underserved in health care
- A health outcome that is worse in these populations *compared to a reference population group* defines a health disparity



Relative risk of All-Cause Mortality by US Annual Household Income Level

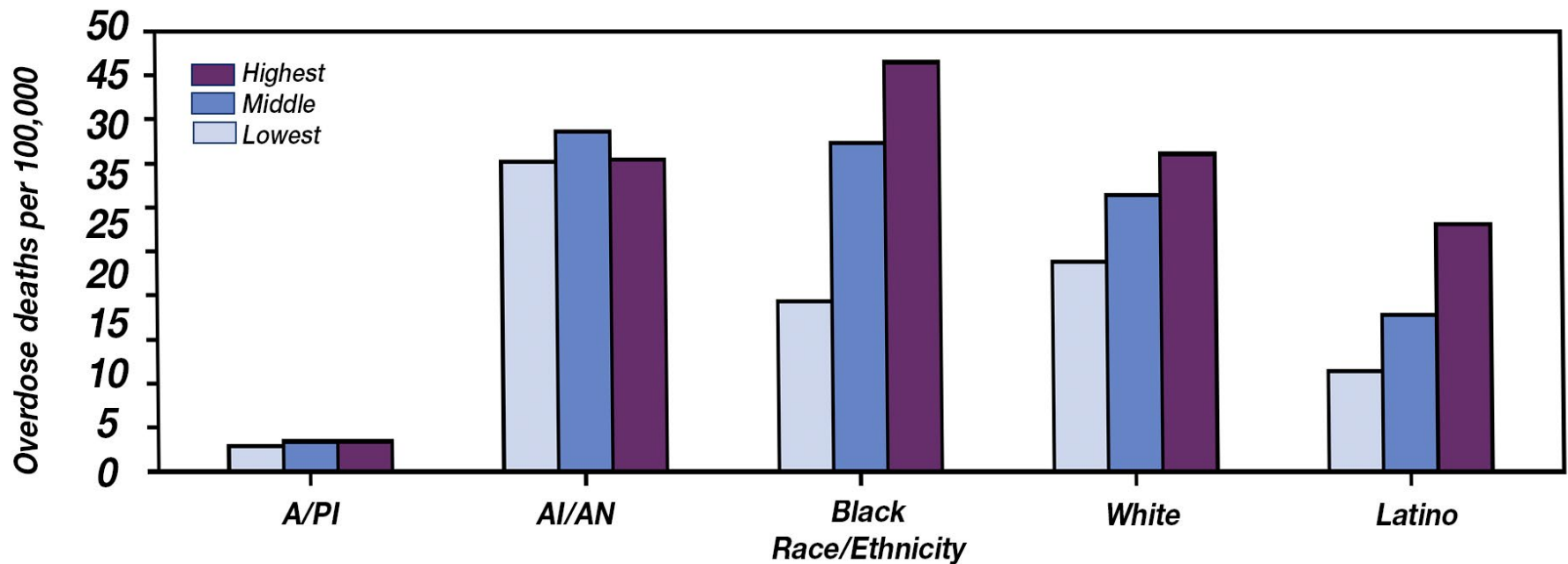


More Educational Attainment Has More Impact on Black Persons than White Persons in Reducing Later Life Dementia



Age Adjusted Overdose Deaths by Race/Ethnicity and Income Inequality

25 States and DC, 2019-2020; *MMWR* 2022; 71:29: 940-947



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Best Practices for Inclusive Participation in Clinical Studies

- **Recruitment of participants with plan for target sample size to start**
- **Tailor recruitment strategies**
- **Community-engaged approach built on mutual trust — CEAL model**
- **Be intentional in achieving targets by population group**
- **Diverse investigator team**
- **Accountability in publication**



Inclusive Participation in NIH-Funded Research: Looking Forward

- Mutually exclusive categories by race and ethnicity
- Decrease unknowns to <5% – EHR challenge
- Achieve demographic and meaningful representation
- Support a community-engaged platform to promote participation
- **Require standardized measure of SES**
- Accountability of investigators plans and annual reports



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