NIMHD Perspectives on Minority Inclusion in Health Research

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

- 2016: 36.4%
- 2017: 28.3%
- 2018: 29.3%
NIH Racial and Ethnic Minority Enrollment, US Sites, NIH-Defined Phase 3 Studies FY2016-FY2018

![Graph showing percent enrollment from 2016 to 2018. The enrollment percentage decreases from 42.6% in 2016 to 22.4% in 2017, then increases to 31.1% in 2018.](image-url)
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!

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