National Institute of Nursing Research
Strategies to Strengthen Inclusion in NINR-Supported Studies Working Group
Final Report of Recommendations

September 2022

TABLE OF CONTENTS

Executive Summary **1**

Background **3**

Purpose and Charge 3

Committee Approach to Addressing the Charge 3

Recommendations to Increase Inclusion in NINR-Supported Research Participation **5**

Recommendation A: Promote Engagement with Populations Underrepresented in Biomedical Research 5

Recommendation B: Incentivize Inclusion through Responsiveness to Funding Initiatives and Scientific Review 6

Recommendation C: Close Research Gaps on the Most Pressing Health Problems Experienced by Populations Underrepresented in NINR-Funded Studies through Training and Education on Translation, Dissemination, and Implementation 7

Conclusion **8**

Appendix A: Working Group Member List **9**

Appendix B: NIH and NINR Policies **10**

Appendix C: Research Inclusion Related Data **11**

Executive Summary

The National Institute of Nursing Research (NINR) convened a Working Group on the *Strategies to Strengthen Inclusion in NINR-Supported Studies Working Group (WGI; the Working Group)* under the auspices of the National Advisory Council for Nursing Research (NACNR). The Working Group's charge was to review participant inclusion in NINR-supported studies and to consider the range of factors that may affect it—such as principal investigator and research team expertise, research topics, study design, inclusion and exclusion criteria, recruitment strategies, and National Institutes of Health (NIH) policies. The WGI met monthly between February 2022 and September 2022 to discuss data, policy, and research relevant to inclusion of populations that are underrepresented in biomedical and NINR-supported research. The Working Group developed three overarching recommendations and suggested implementation strategies associated with each recommendation, as well as brief statements to provide context for each of the overarching recommendations.

The Working Group intends for these recommendations to facilitate bold action on the part of NINR to address crucial issues of diversity and equity in participant inclusion with the aim of advancing good science and ensuring that all benefit from scientific advancement.

Promote Engagement with Populations Underrepresented in Biomedical Research

NINR must maximize inclusion of populations underrepresented in biomedical research to promote translation, implementation, and dissemination of NINR-supported research.

- Partner with other NIH Institutes, Centers, and Offices (ICOs) and federal and community organizations to develop regional training programs designed to address special issues related to inclusion of diverse populations in biomedical research.
- Partner with other NIH ICOs and federal and community organizations to develop and implement webinars on the benefits of participation in biomedical research.
- Use phased funding announcements to provide investigators with the opportunity to incorporate a community engagement phase, where investigators are granted sufficient time or funding to build relationships with communities often underrepresented in biomedical research. Examples of meaningful community engagement range from community members developing a sense of ownership in the research to investigators to members of the community working towards mutual success in addressing issues that impact community well-being.

Incentivize Inclusion through Responsiveness to Funding Initiatives and Scientific Review

NINR should prioritize investigator efforts to include populations often not represented in NINR-supported research—through investigator training opportunities, inclusion responsiveness criterion in funding opportunities, and application review.

- Require diverse study participant inclusion and studies powered to report fundings by race, ethnicity, and gender as a responsiveness criterion in funding opportunities. Partner with the NIH Center for Scientific Review to pilot additional review criteria that makes scientifically relevant inclusion of underrepresented study participants scoreable.
- Develop and execute applicant webinars that provide potential applicants with specific information about NIH ICOs' expectations for scorable and scientifically relevant inclusion criteria.
- Ensure that NINR funding opportunity announcements encourage a diverse investigative team (e.g., inclusion of members from the target community, multiple/co-principal investigators from

underrepresented backgrounds, and/or training opportunities for researchers from underrepresented backgrounds) as a responsiveness criterion (when scientifically relevant).

Close Research Gaps on the Most Pressing Health Problems Experienced by Populations Underrepresented in NINR-Funded Studies through Training and Education on Translation, Dissemination, and Implementation

NINR should promote rigorous study designs that incorporate engagement, inclusion, and retention of participants from underrepresented, understudied, or small population groups.

- Partner with other NIH ICOs and other funding agencies to support initiatives that encourage the development of innovative research methods that are applicable to studies of underrepresented and understudied populations (especially small subpopulations).
- Provide training for potential principal investigators on topics such as the engagement, inclusion, and retention of study participants from underrepresented, understudied, or small populations; the definition of small sample populations; research design and analytic considerations; and evaluation of intervention studies with small sample populations.

Background

Purpose and Charge

The National Institute of Nursing Research (NINR) is dedicated to solving the Nation's most pressing and persistent health challenges and informing practice and policy to optimize health and advance health equity. In order to understand and overcome health inequities and improve health outcomes across all populations, it is essential that research participation is inclusive of all. This is especially true for those in populations that have been historically underrepresented.

To this end, NINR convened the *Strategies to Strengthen Inclusion in NINR-Supported Studies Working Group (WGI; the Working Group)* under the auspices of the National Advisory Council for Nursing Research (NACNR) with a charge to review participant inclusion in NINR-supported studies and to consider the range of factors that may affect it—such as principal investigator and research team expertise, research topics, study design, inclusion and exclusion criteria, recruitment strategies, and National Institutes of Health (NIH) policies. The WGI was comprised of experts from a health care system, nursing administration, academia (e.g., nursing science and public health), the community (e.g., representatives of faith-based organizations). The WGI also included a member of the NACNR; NIH staff outside of NINR; an NINR Extramural Program Official; and a liaison from the NINR Office of Science, Policy, and Legislation. A full list of WGI members can be found in **Appendix A**.

The Working Group was tasked with identifying priority barriers to inclusive research, developing associated strategies to address these barriers, and making recommendations with the goal of increasing diversity and inclusion in NINR-supported research.

Committee Approach to Addressing the Charge

The WGI met monthly between February 2022 and September 2022 and structured their discussions over this time period by addressing the following:

- The Why?
  - The Problem
- The What?
  - Actionable Strategies
- The How?
  - Implementation Approaches

WGI Co-Chairs guided the discussion towards identifying the scope of the problem and barriers to inclusion ("The Why"), the actionable strategies that could address identified barriers ("The What"), and the implementation approaches that NINR could take to increase diverse participant inclusion ("The How"). WGI members reviewed NIH policies related to inclusion as part of the "The Why?" discussion. They used these policies as guardrails to guide their overall discussions about inclusion in NINR-supported studies. These policies included the NIH Revitalization Act of 1993, the 21st Century Cures Act, and the NIH Inclusion Across the Lifespan policy. Details of these policies can be found in **Appendix B**. In addition to the groups of focus included in the aforementioned policies, the WGI gave consideration to inclusion of potential study participants from sex and gender minority (SGM) populations. While SGM populations are not explicitly included in the policies that served as guardrails for the workgroup, Working Group members expressed that it was important to include this group in each discussion and during the development of recommendations.

WGI members reviewed race/ethnicity data from the NINR report, “Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research” for fiscal years 2016 to 2018 and 2019 to 2021 (Appendix C, **Figure 1**, **Figure 2**) Review of data from these reports revealed that the median participation among African American/Black populations in NINR-supported research was significantly higher than NIH-supported research (Appendix C, **Figure 1**). Additionally, median research participation among White populations and women was higher at NINR relative to NIH (Appendix C**,** **Figure 1**, **Figure 3).** Data on SGM populations were not available to the Working Group.

To better understand the diversity of NINR-supported investigators, WGI members reviewed the race/ethnicity of NINR-supported investigators relative to the larger NIH. These data revealed that NINR awarded higher proportions of grants to female investigators, non-Hispanic investigators, and White investigators than NIH (Appendix C, **Figure 4**).

To understand how NINR grants were disbursed across geographical areas with high concentrations of diverse population groups, WGI members reviewed diversity indices of US states from 2020 as compared to geographical locations of NINR grant awards between 2019 and 2020. These data showed that NINR grant awards tended cluster in states with high diversity indices, specifically in New York, California, Massachusetts, Pennsylvania, Ohio, North Carolina, and Texas (Appendix C, **Figure 5**).

The WGI also reviewed data on NINR grants funded between 2017 and 2021, which showed that approximately 63 percent of NINR-funded grants supported research on health disparities, minority health, and/or rural health studies (Appendix C, **Figure 6**).

WGI members considered the frequency of NINR active funding collaborations with other NIH Institutes, Centers, and Office (ICOs). The most frequent NINR collaborators were the National Institute on Minority Health and Health Disparities (NIMHD), the National Institute of General Medicine Sciences (NIGMS), the National Institute of Neurological Disorders and Stroke (NINDS), and the Office of the NIH Director (Appendix C, **Figure 7**).

Additionally, WGI members shared published resources within the group on the benefits of diverse participant inclusion in research.

Based on the WGI review of the diversity of NINR’s participant inclusion and associated factors, WGI members were asked to consider the barriers and facilitators to diverse inclusion in research across the participant, investigator, and structural/institutional levels. The outcomes of this exercise were also considered in the development of recommendations for NINR in the context of the Institute’s policies and resources. Below are general descriptions of WGI considerations discussed at each level:

- At the *participant level*, the WGI considered the factors directly related to the patient, client, and/or participant barriers to participation in research (e.g., distrust of researchers, lack of knowledge about the clinical research process, privacy concerns).
- At the *investigator level*, the WGI considered the factors related to investigator barriers to the inclusion of diverse study participants in their research (e.g., trial design, site selection, understanding of NINR inclusion policies).
- At the *structural/institutional level*, the WGI considered factors that shape investigator actions and participant enrollment patterns in research (e.g., policies, resources). WGI Co-Chairs emphasized that NINR can impact research participation at the structural/institutional level.

After the Working Group generated a list of barriers and promoters of inclusion at the participant, investigator, and structural/institutional levels, they identified actionable strategies that could address those barriers. These strategies were prioritized using the following criteria: 1) the feasibility of NINR to address the barrier, 2) the timeline in which the barrier could be addressed (i.e., short- [6 to 12 months], intermediate- [12 to 24 months], and long-term [24 to 60 months]), and 3) metrics for evaluating whether a select strategy met its goal or not.

Recommendations to Increase Inclusion in NINR-Supported Research Participation

After reviewing data and policies related to research participant inclusion; identifying barriers and promoters of inclusion across individual, investigator, and structural/institutional levels; and prioritizing the actionable strategies that would be most impactful, the WGI developed three overarching recommendations and associated strategies for NINR to consider (Figure 8). The WGI members put forward these recommendations and associated strategies as nonlinear approaches that will intertwine to bring about inclusive participation in NINR-supported research.

Figure 8. WGI recommended three overarching approaches for promoting inclusion in NINR-funded research

Recommendation A: Promote Engagement with Populations Underrepresented in Biomedical Research

NINR must maximize inclusion of populations underrepresented in biomedical research to promote translation, implementation, and dissemination in NINR-support research.

WGI members talked about challenges in engaging participants from population groups historically underrepresented in biomedical research. Investigators often fail to focus research on topics that are important to or that meet the needs of their target community (e.g., patient, geographic, organizational, or racial/ethnic), which can lead to mistrust or disinterest from underrepresented participants. A common challenge to NINR investigators is insufficient time or funding to build relationships or engage with underrepresented communities in a meaningful way, which challenges their ability to understand and meet the needs of these individuals and communities. Meaningful community engagement, alignment of research topics to the needs and interests of underrepresented communities, and funding to trusted community-based organizations, promote engagement with and increase participation from underrepresented individuals.

The WGI identified three strategies to promote engagement with populations underrepresented in biomedical research that could be implemented by NINR in the short-term (6 to 12 months) and continued in the long-term (24 to 60 months). These were:

Strategy A1: Partner with other NIH Institutes, Centers, and Offices (ICOs) and federal and community organizations to develop regional training programs designed to address special issues related to inclusion of diverse populations in biomedical research.

Strategy A2: Partner with other NIH ICOs and federal and community organizations to develop and implement webinars on the benefits of participation in biomedical research.

Strategy A3: Use phased funding announcements to provide investigators with the opportunity to incorporate a community engagement phase, where investigators are granted sufficient time or funding to build relationships with communities often underrepresented in biomedical research. Examples of meaningful engagement range from the community developing a sense of ownership in the research to investigators and community working towards mutual success addressing issues that affect community well-being.

WGI members discussed metrics for these proposed strategies that NINR could use to measure success. These included the percentage of applications requesting a community engagement phase, the number and amounts of awards targeting populations historically underrepresented in biomedical research, funding to community-based partners, participation in design and implementation in keeping with standards of community-based participatory research approaches, and number of participants from historically underrepresented populations.

Recommendation B: Incentivize Inclusion through Responsiveness to Funding Initiatives and Scientific Review

NINR should prioritize investigator efforts to include populations often not represented in NINR-supported research—through investigator training opportunities, inclusion responsiveness criterion in funding opportunities, and application review.

WGI members discussed how historically underrepresented individuals may be more comfortable participating in research when a member of the research team is also a member of that underrepresented population and/or when there is inclusion of trusted community-based organizations as funded partners. However, historically underrepresented investigators may not have access to the resources or training needed for success in the NINR funding process. Further, the inclusion of underrepresented population groups is not prioritized during the application review process. Working Group members also determined that NIH guardrail policies (i.e., the NIH Revitalization Act of 1993, the 21st Century Cures Act, and the NIH Inclusion Across the Lifespan policy) do not include requirements for investigators to provide scientific rationale for inclusion or exclusion of potential participant groups, nor for the inclusion of a comparison group. Further, investigators are required to propose sub-group analyses, but that requirement is often not explicitly scored in application review and there is no clear policy scoring study design powered to report data by sub-group, nor for tracking sub-group analyses after award.

The WGI identified two strategies to incentivize inclusion through training opportunities, funding opportunities, and application review that could be implemented in the short-term (i.e., 6 to 12 months). These were:

Strategy B1: Require diverse study participant inclusion and studies powered to report fundings by race, ethnicity, and gender as a responsiveness criterion in funding opportunities. Partner with the NIH Center for Scientific Review to pilot additional review criteria that makes scientifically relevant inclusion of underrepresented study participants scoreable.

Strategy B2: Develop and execute applicant webinars that provide potential applicants with specific information about NIH ICOs' expectations for scorable and scientifically relevant inclusion criteria.

Strategy B3: Ensure that NINR funding opportunity announcements encourage a diverse investigative team (e.g., inclusion of members from the target community, multiple/co-principal investigators from underrepresented backgrounds, and/or training opportunities for researchers from underrepresented backgrounds) as a responsiveness criterion (when scientifically relevant).

WGI members discussed potential metrics for these strategies that NINR could use to measure success. These included number of webinars provided to increase knowledge about inclusion criteria and the percentage of grantees who attend at least one of these webinars. Additionally, NINR could track the rate of success in applications with investigative teams that include underrepresented investigators and the proportion of applications meeting inclusion responsiveness criteria.

Recommendation C: Close Research Gaps on the Most Pressing Health Problems Experienced by Populations Underrepresented in NINR-Funded Studies through Training and Education on Translation, Dissemination, and Implementation

NINR should promote rigorous study designs that incorporate engagement, inclusion, and retention of participants from underrepresented, understudied, or small population groups.

Health equity research and good science involve participation from populations underrepresented in biomedical research. However, these population groups are often overlooked because they are small and/or geographically dispersed. WGI members discussed the importance of promoting methodologically innovative solutions to the challenges involved in the research design and analytics of underrepresented, understudied, or small population groups so that meaningful inferences can be made.

The WGI identified two strategies to promote the rigorous study of small populations that would produce meaningful outcomes to improve the health of these historically underrepresented population groups. The Working Group determined that these strategies could be implemented within NINR in the short-term (i.e., 6 to 12 months).

Strategy C1: Partner with NIH ICOs and other funding agencies to support initiatives that encourage the development of innovative research methods that are applicable to studies of underrepresented and understudied populations (especially small population groups).

Strategy C2: Provide training for potential principal investigators on topics such as the engagement, inclusion, and retention of study participants from underrepresented, understudied, or small populations; the definition of small sample populations; research design and analytic considerations; and evaluation of intervention studies with small sample populations.

WGI members discussed potential metrics for these strategies that NINR could use to measure success. These included the number of currently funded NINR investigators who attend training, the number of training participants who submit NINR grant applications, and the proportion of applications that use the innovative methodologies learned in training.

Conclusion

The WGI utilized a data-, policy-, and research-driven multidisciplinary approach to determine high priority, short-term and long-term strategies that would promote research participation from populations historically underrepresented in NINR-funded research. The WGI developed three recommendations and associated strategies that NINR could implement to ensure the participation of all populations in NINR-supported research and to better understand and overcome health inequities. Moreover, the Working Group intends for these recommendations to facilitate bold action on the part of NINR to address crucial issues of diversity and equity in participant inclusion with the aim of advancing good science and ensuring that all benefit from scientific advancement.

Appendix A: Working Group Member List

Co-Chairs
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Catherine Timura, PhD
(NINR Liaison)
Health Policy Analyst
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Appendix B: NIH Policies

The NIH Revitalization Act of 1993 ensures that:

- Women are included as subjects in each project of such research.
- Members of minority groups are included in such research.
- Enrollment data must be reported by sex/gender, race and ethnicity from all grants and contracts with human subjects (grants only analyzing existing data excluded).

And directs NIH to specify:

- Circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate.
- The manner in which clinical trials are required to be designed and carried out.
- The operation of outreach programs.

The 21st Century Cures Act, PL 114-255, enacted December 13, 2016:

- Requires triennial inclusion reporting from all Institutes by research, condition, and disease categories (RCDC).
- Requires entities conducting applicable clinical trials submit results of valid analyses by sex/gender, race, and ethnicity in Clinicaltrials.gov.
- Requires that NIH consider, as appropriate, whether the entity has complied with this reporting requirement when awarding any future grant to that entity.
- As of 11/28/2017, this requirement applies to applicable NIH-defined Phase III clinical trials involving research subjects of all ages, including foreign awards and domestic awards with a foreign component.

The NIH Inclusion Across the Lifespan policy, as of January 25, 2019 ensures that

- Individuals of all ages, including children (i.e., individuals under the age of 18) and older adults, must be included in all human subjects research, conducted, or supported by the NIH, unless there are scientific or ethical reasons not to include them.
- Applications/proposals must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed.
- If individuals will be excluded from the research based on age, the recipient/offeror must provide an acceptable justification for the exclusion.
- NIH recipients/offerors must submit data on participant age at enrollment in progress reports.
- Inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

Appendix C: Research Inclusion Related Data

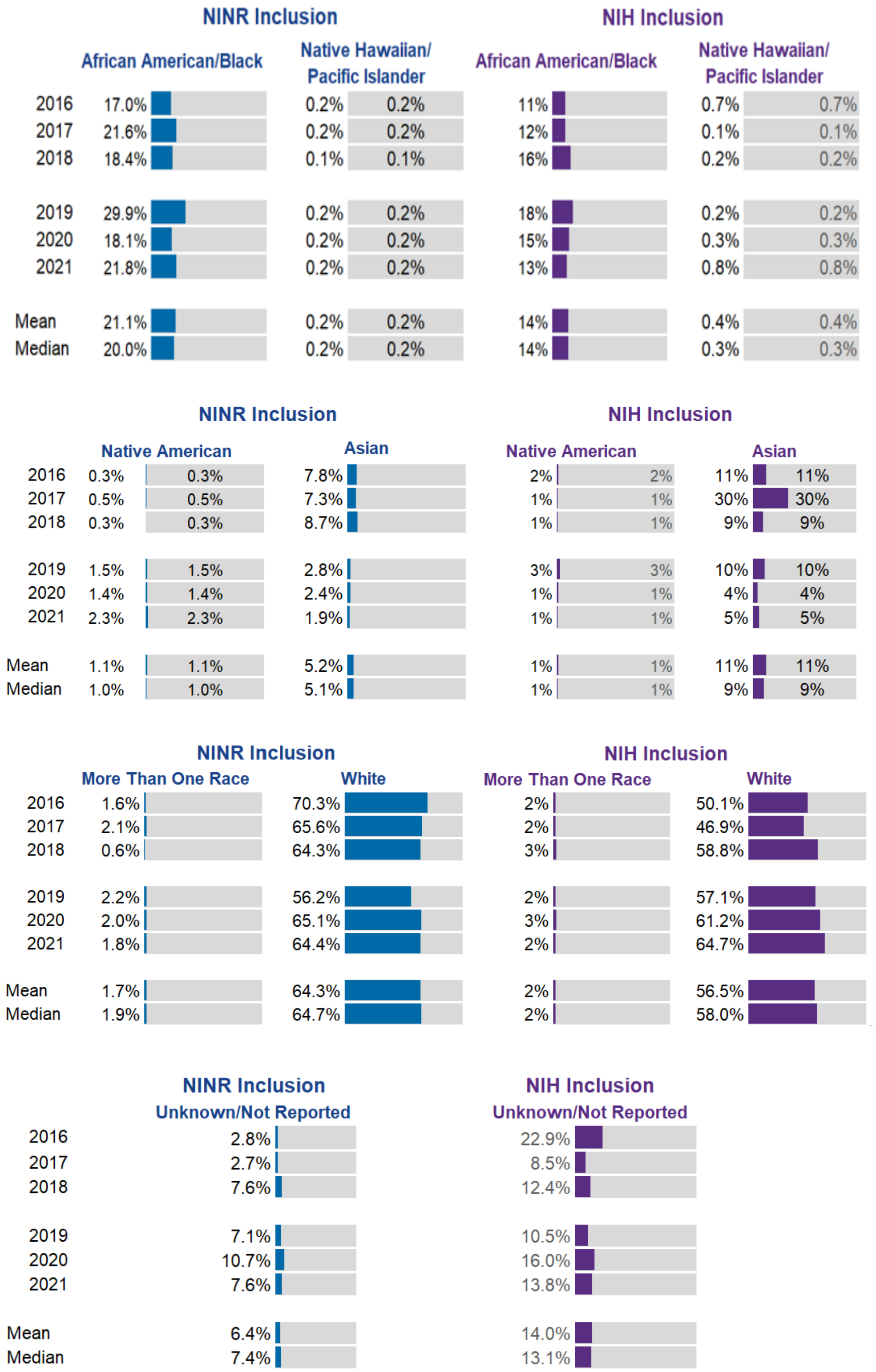

Figure 1. Participant inclusion by race in NINR and NIH clinical research from 2016 to 2021

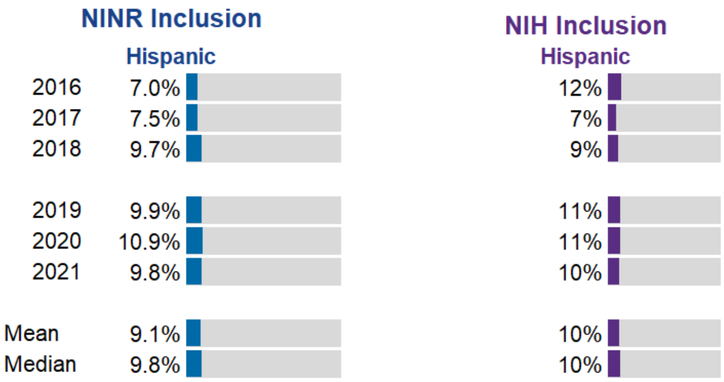

Figure 2. Participant inclusion by ethnicity in NINR and NIH clinical research from 2016 to 2021

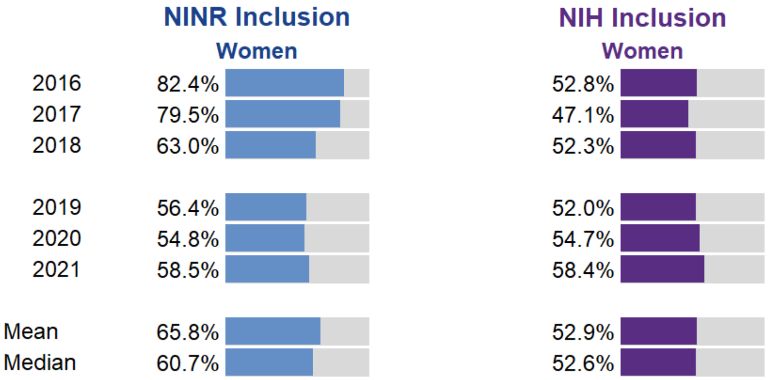

Figure 4. Participant inclusion by sex in NINR and NIH clinical research from 2016 to 2021

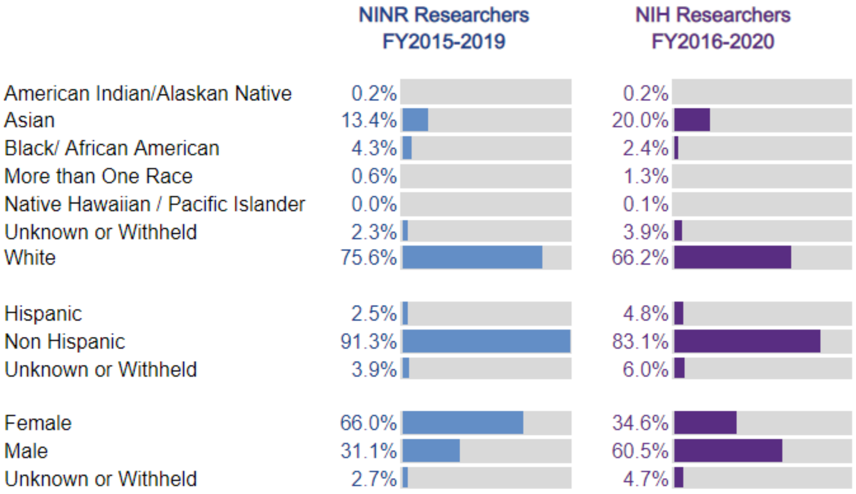

Figure 3. Race, ethnicity, and sex of NINR and NIH Research Workforce (includes Rs, Ks, and SBIR/STTR)

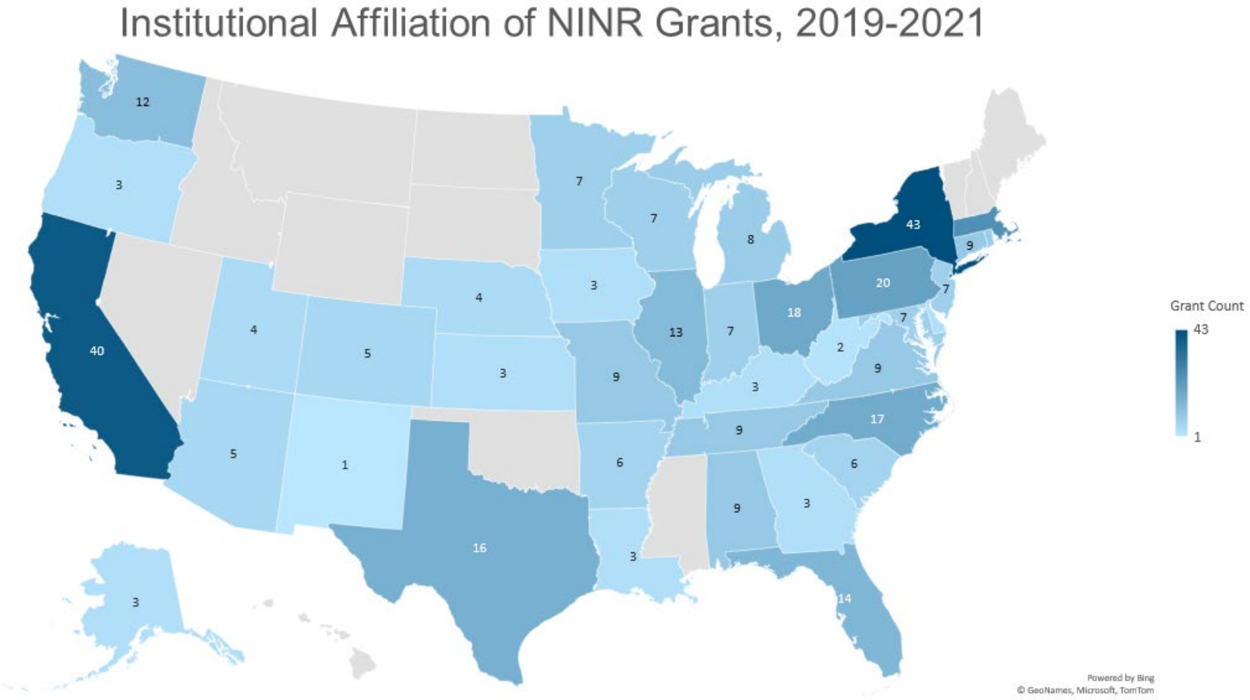

Figure 5. NINR grants from 2019 to 2021 cluster significantly on both United States coasts. The largest number of grants were awarded to institutions in New York, California, Massachusetts, Pennsylvania, Ohio, North Carolina, and Texas

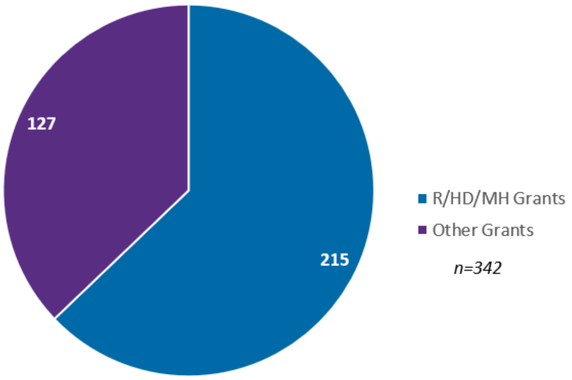

Figure 6. NINR grants supporting rural health, health disparities, and minority health. These categories are not mutually exclusive.

Figure 7. Active cross-NIH opportunity collaborations with NINR