Rethinking Race and Ethnicity in Biomedical Research:

Health Research Alliance Call

BRIEFING BOOK

February 20, 2025

1:00 – 2:00 pm ET

Registration Link:
https://healthra.zoom.us/meeting/register/4pJqsjMkTFa2Et5xl7wBEA

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Rethinking Race and Ethnicity in Biomedical Research: Health Research Alliance Virtual Meeting

February 20, 2025

PURPOSE AND OBJECTIVES

A National Academies committee published a report to review existing guidance and provide recommendations to the scientific community about the use of race and ethnicity in biomedical research. On February 20, 2025, the report authors will join a virtual meeting with the Health Research Alliance to discuss the study report's key messages and recommendations. Questions from the audience about the report are welcome.

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THURSDAY, FEBRUARY 20, 2025

1:00 – 2:00 pm ET

1:00 – 1:05 PM ET	**Welcome and Introduction to the Session** **KAVITA BHALLA,** *Health Research Alliance DEI Co-lead* Conquer Cancer, ASCO Foundation **ZOË FUCHS,** *Health Research Alliance DEI Co-lead* TSC Alliance **LINDSEY REDMAN RIVERA,** *Health Research Alliance DEI Co-lead* Health Resources in Action
1:05 – 1:30 PM	**Overview of the Report** **CARMEN GUERRA,** *Committee Member* University of Pennsylvania **NEIL POWE,** *Committee Member* University of California, San Francisco **ROLAND THORPE,** *Committee Member* Johns Hopkins University
1:30 – 1:50 PM	**Q&A with Committee Members** Moderated by Kavita Bhalla, Zoë Fuchs, and Lindsey Redman Rivera
1:50 – 2:00 PM	**Closing Remarks** Kavita Bhalla, Zoë Fuchs, and Lindsey Redman Rivera
2:00 PM	***Adjourn***

Committee on the Use of Race and Ethnicity in Biomedical Research

Committee Biographies

To access the biosketches of the full committee, visit the following webpage:
https://www.nationalacademies.org/our-work/the-use-of-race-and-ethnicity-in-biomedical-research#sectionCommittee

Carmen Guerra, M.D., M.S.C.E., is the Ruth C. and Raymond G. Perelman Professor of Medicine at the Perelman School of Medicine at the University of Pennsylvania. She is also the Vice Chair of Diversity and Inclusion for the Department of Medicine, and the Associate Director of Diversity and Outreach for the Abramson Cancer Center (ACC) where she leads Community Outreach and Engagement, including a Genentech-funded Cancer Clinical Trials Ambassador Program that promotes clinical trial awareness through peer-to-peer education. A general internist trained in epidemiology and a health equity researcher, Dr. Guerra has designed and evaluated interventions to increase access to cancer screening and cancer clinical trials for underserved populations. Dr. Guerra serves on the American Cancer Society's Guideline Development Group and is an author of the American Cancer Society's current colorectal, cervical, and lung cancer screening guidelines as well as the current HPV vaccination guidelines. In recognition of her contributions, Dr. Guerra received the American Cancer Society's St. George Medal in 2017, the Association of Community Cancer Centers Research Award in 2022, and the American Society of Clinical Oncology Excellence in Health Equity Award in 2023. She is also a member of the advisory board of Guardant Health, a company developing blood tests for colorectal cancer, and is the US Deputy Chair of the Health Equity Workgroup of the Multicancer Early Detection Consortium.

Neil R. Powe, M.D., M.P.H., M.B.A., is Chief of Medicine at the Priscilla Chan and Mark Zuckerberg San Francisco General Hospital and the Constance B. Wofsy Distinguished Professor at the University of California, San Francisco. He also serves as the Chief Science Officer for the Commonwealth Fund. Dr. Powe led the National Kidney Foundation-American Society of Nephrology Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases that led to elimination of race from estimation of kidney function. As member and now chair of the Journal of the American Medical Association Oversight Committee, he provided important decision making regarding a podcast on structural racism that was published in JAMA. Dr. Powe is a member of the National Academy of Medicine and has served on previous National Academies consensus study committees. Among his honors are the Diversity Award from the Association of Professors of Medicine, the John M. Eisenberg Award for Career Achievement in Research and the Robert J. Glaser Award from the Society of General Internal Medicine, the David Hume Memorial Award from the National Kidney Foundation, the 2021 John Phillips Memorial Award for Distinguished Contributions in Clinical Medicine from the American College of Physicians, and the Cato Laurencin Lifetime Research Award from the National Medical Association. Dr. Powe holds an M.D. and M.P.H from Harvard, and at the University of Pennsylvania, he completed residency, was a Robert Wood Johnson Clinical Scholar, and earned an M.B.A.

Roland J. Thorpe, Jr., Ph.D., is a professor in the Department of Health, Behavior, and Society, founding director of the Program of Men's Health Research in the Hopkins Center for Health Disparities Solutions, and director of the Johns Hopkins Alzheimer's Disease Resource Center for Minority Aging Research at the Johns Hopkins Bloomberg School of Public Health. Dr. Thorpe is a social epidemiologist and gerontologist whose research focuses on how social determinants of health affect health and functional outcomes among men across the life course. Dr. Thorpe serves as principal investigator (PI) on several National Institutes of Health–funded grants and is a multiple PI of the Artificial Intelligence/Machine Learning consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD). Dr. Thorpe is the inaugural associate vice provost for faculty diversity at Johns Hopkins University. He is a fellow of the Gerontological Society of America and the Academy of Behavioral Medicine Research. Dr. Thorpe earned a bachelor's in theoretical mathematics from Florida A&M University, a master's in statistics, and a Ph.D. in clinical epidemiology with a graduate minor in gerontology from Purdue University. He received postdoctoral training in health disparities and gerontology from the Division of Geriatric Medicine and Gerontology at the Johns Hopkins School of Medicine. Dr. Thorpe is a member of scientific advisory boards, including the National Center for Health Statistics Board of Scientific Counselors, and is the editor-in-chief of *Ethnicity & Disease*.

Statement of Task

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will assess the current use of the social constructs of race and ethnicity in biomedical research and provide recommendations to guide the scientific community in the use of race and ethnicity in biomedical research.

More specifically, the committee will:

- Document and evaluate how racialized group and ethnic categories are currently being used in biomedical research (e.g., as a descriptor, to stratify data, to apply race norming, to infer differences between groups due to environmental and social impacts), including describing consequences and contributions to health inequities in current clinical practices;
- Identify the circumstances in which it is appropriate to use the social constructs of race and ethnicity in biomedical research, for example in studying the health effects of racism, and the circumstances in which race and ethnicity should not be used to inform inferences;
- Review existing guidance for researchers on the use of race as a variable in biomedical research.

Based on its review of the literature and other expert input, the committee will develop a report with its findings, conclusions, and recommendations for entities such as researchers, funders, publishers, scientific and medical societies, health systems, and industry regarding:

- The use of race and ethnicity in biomedical research, including identifying current practices that should be continued, stopped, or modified;
- Policy changes to reform the use of race and ethnicity in biomedical research, with specific attention to the practice of race norming or race correction;
- Implementation strategies to help enhance the adoption of best practices across the biomedical research community.

The committee’s work will focus on the use of racialized group and ethnic categories across the spectrum of biomedical research, including the development of clinical prediction models and other clinical decision tools. Related topics in the provision of clinical care, such as inequitable access to health care and racism in care delivery, are beyond the scope of this study.

NATIONAL ACADEMIES Sciences Engineering Medicine

Consensus Study Report
Highlights

Rethinking Race and Ethnicity in Biomedical Research

Using race and ethnicity to categorize individuals is ingrained in American society, including in health care and biomedical research, and these characteristics impact identity and how individuals experience the world. Although these social attributes have no biological basis—meaning race and ethnicity do not explain genetic variation, nor do they determine disease onset and progression—they are still regularly used in biomedical research, sometimes in harmful ways. Even so, these attributes can be useful in some circumstances, especially if carefully considered and tailored throughout the research process. Given this complexity, researchers need guidance in deciding if, when, and how to use race and ethnicity in their work.

The Doris Duke Foundation and the Burroughs Wellcome Fund asked the National Academies of Sciences, Engineering, and Medicine to convene a committee to assess the current use of racial and ethnic categories in biomedical research, review existing guidance, and provide recommendations to guide future use. *Rethinking Race and Ethnicity in Biomedical Research* provides nine actionable recommendations and associated resources for advancing the responsible use of race and ethnicity. The recommendations provide detailed guidance for researchers on how to decide whether race and ethnicity should be used, decision-making data that should be included in applications and publications, how to conduct research responsibly and with a clear scientific rationale, best practices for developing health technologies, and approaches to support sustained community engagement.

USE OF RACE AND ETHNICITY IN BIOMEDICAL RESEARCH

The U.S. Office of Management and Budget (OMB) provides federal agencies with standard categories for collecting race and ethnicity data. In biomedical research, these categories are often required for reporting research participant enrollment demographics and are found in readily available datasets. Although the OMB directive explicitly states that these categories are sociopolitical constructs, their intended purpose is often misunderstood or conflated with use in scientific analyses. This has contributed to a persistent misconception that humans can be divided into biologically separate groups, an idea known as "race science" which has been disproven by decades of research. In fact, clusters of genetic variants—such as the high propensity of sickle cell disease among Black individuals—are due to geographic distribution or ancestry rather than race. In addition, individual characteristics like skin or eye color can be partially explained through genetic inheritance but are complex traits that are oversimplified by racialized associations.

Although race and ethnicity are not rooted in biology, they do shape social realities and lived experiences, and their manifestations—including health disparities and structural racism—can be correlated with biological systems and health. The report concludes that race has been emphasized at the expense of exploring concepts like racism which may more directly impact health, and existing evidence will need to be rebuilt to specifically consider the role of racism and other related concepts (see **Conclusion 6-12** in the report).

PARTNERING WITH COMMUNITIES

Thoughtful and sustained community engagement and partnerships are essential for conducting research aligned with ethical and scientific principles and must become part of the scientific process, rather than viewed as an exercise that is beneficial but optional. Additionally, only individuals can share how race, ethnicity, and related concepts impact their experiences—vital data for research focusing on topics like health disparities—and community engagement efforts should be designed to accommodate community contexts like the sovereignty of American Indian or Alaska Native Tribes. Therefore, the report recommends that

- Researchers collecting and using race and ethnicity data should partner with relevant communities to optimize authentic, continuous, and sustained engagement, undergirded by mutual trust (see **Recommendation 7** in the report); and
- Funders should provide resources and timelines that encourage these collaborations and require, as appropriate, community engagement plans in applications (see **Recommendation 9** in the report).

APPROPRIATE USE OF RACE AND ETHNICITY THROUGHOUT THE BIOMEDICAL RESEARCH PROCESS

The report concludes that deciding to either use or omit race and ethnicity has advantages and disadvantages and requires careful deliberation (see **Conclusion 6-1** in the report). Even for well-intentioned purposes, like recruiting a diverse cohort, the correct approach to using race and ethnicity will depend on the research question and specific context. The report recommends that researchers evaluate and decide whether the use of race and ethnicity is appropriate and scientifically justified at every stage in the biomedical research process, including

- Identifying how the historical or social context affects the evidence base,
- Understanding the context and requirements for partnering with specific communities,
- Considering potential benefits or harms of collecting race and ethnicity information,
- Refraining from making unsupported inferences related to racial and ethnic categories, and
- Articulating these decisions and their limitations in all publications (see **Recommendation 1** in the report).

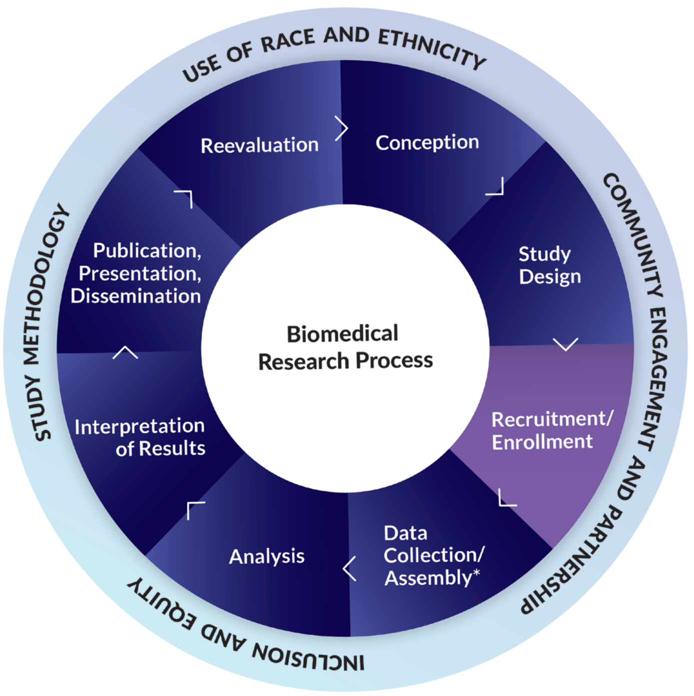
Once researchers decide to use race and ethnicity in their work, they should thoughtfully consider whether these attributes are being used as a proxy—or stand-in—for another variable, such as social determinants of health, that would better address the research question. If race and ethnicity are the appropriate attributes, the researcher should provide an operational definition of race and ethnicity in all applications, manuscripts, and related products, including an explanation of their rationale and attributes of data provenance (see **Recommendation 2** in the report). Researchers should also strive to identify which concepts often conflated with race or ethnicity are relevant to their study, and once identified, select applicable measures (see **Recommendation 4** and **Table 6-1** in the report).

Ensuring appropriate inclusion should be considered at each stage of the study process. Participants are often left out of analyses due to missing race and ethnicity data, small group sizes, a lack of categories that adequately fit their identity, or selection of multiple race and ethnicity categories. The report encourages considering methods that retain as much information about individuals as possible while acknowledging the statistical and practical challenges surrounding small group sizes. The report recommends all racial and ethnic category inclusions and exclusions for analyses be based on scientific rationale motivated by the research question and that researchers should

- Consider oversampling for smaller populations to ensure their inclusion in analysis;
- Justify the choice of reference population; and
- Avoid aggregating participants into nonspecific categories like "Other" or "non-White," as this approach can overlook diverse experiences and inappropriately reinforce White as the norm (see **Recommendation 5** in the report).

Researchers should also consider the inclusion and analysis of multiracial and multiethnic participants at every stage of the research process, including

- Ensuring that participants can select multiple races, ethnicities, or ancestries; and
- Using a classification scheme that includes multiracial and multiethnic people and is based on the research question or context (see **Recommendation 6** and **Table 5-1** in the report).



Use of Race and Ethnicity
- Disaggregate race and ethnicity
- Define concepts and measurements
- Disclose limitations

Community Engagement and Partnership
- Build trust
- Sustain community partnerships
- Ensure transparency
- Respect data sovereignty
- Form interdisciplinary study teams, including community members

Inclusion and Equity
- Account for time for outreach
- Ensure equitable benefit sharing with the community
- Incorporate multi-racial and multi-ethnic individuals

Study Methodology
- Collect more granular data
- Use appropriate categories and measurements for analysis
- Disclose limitations of legacy datasets

● Applies to all studies
● May not apply to studies not recruiting participants
● Should be considered at every research stage

*Researchers conducting observational studies with existing data may enter the cycle here but should consider data provenance and prior stages.

FIGURE 1 Key considerations for the use of race and ethnicity throughout the biomedical research process.

To help operationalize this report's recommendations, the committee identified questions that researchers should thoughtfully consider at each stage of the biomedical research process, illustrated in Figure 1 (see **Box 6-1** in the report for the questions).

SUPPORTING THE APPROPRIATE USE OF RACE AND ETHNICITY IN BIOMEDICAL RESEARCH

Advancing the responsible use of race and ethnicity is not the sole responsibility of individual study teams. The report specifically identifies biomedical technology as a field that must operate transparently at every stage of the development, application, and evaluation of tools that may influence health—including clinical algorithms and artificial intelligence-enabled medical devices—by assessing and reporting on technology performance across a range of racial and ethnic groups (see **Recommendation 3** in the report).

Funders, sponsors, publishers, and editors of biomedical research should also provide consistent guidelines to assist researchers and promote the thoughtful use of race, ethnicity, and related concepts, including

- Requiring researchers to provide a scientific rationale for their use of race and ethnicity, describe data provenance, and acknowledge limitations; and
- Encouraging those developing health technologies to provide datasets, algorithms, and code in an open-source format (see **Recommendation 8** in the report).

LOOKING AHEAD

When implemented, this report's recommendations have the potential to improve the scientific rigor of biomedical research, mitigate bias that continues to affect research and health care, and build lasting trust among researchers and community members. These changes do not need to be daunting—this is an exciting opportunity to ensure that race and ethnicity are used responsibly and do not cause any more harm.

To learn more about this report, visit our website at nationalacademies.org/Race-in-Biomed.

COMMITTEE ON THE USE OF RACE AND ETHNICITY IN BIOMEDICAL RESEARCH **M. ROY WILSON** (*Chair*), Wayne State University; **ALLISON AIELLO,** Columbia University; **EFRÉN FLORES,** Massachusetts General Hospital; **CARMEN GUERRA,** University of Pennsylvania; **ELIZABETH HEITMAN,** University of Texas Southwestern Medical Center; **MATTHEW HUDSON,** Prisma Health; **HUSSEINI MANJI,** UK Govt Mental Health Mission and Oxford University; **AMY MORAN-THOMAS,** Massachusetts Institute of Technology; **MARGARET MOSS,** University of Minnesota School of Nursing; **ELIZABETH OFILI,** Morehouse School of Medicine and Morehouse Choice Accountable Care Organization; **NEIL R. POWE,** Priscilla Chan and Mark Zuckerberg San Francisco General Hospital and University of California–San Francisco; **ALIYA SAPERSTEIN,** Stanford University; **ROLAND J. THORPE, JR.,** Johns Hopkins Bloomberg School of Public Health; **SHYAM VISWESWARAN,** University of Pittsburgh; **GENEVIEVE WOJCIK,** Johns Hopkins Bloomberg School of Public Health, and **RUQAIIJAH YEARBY,** The Ohio State University

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FOR MORE INFORMATION
This Consensus Study Report Highlights was prepared by National Academies staff based on the Consensus Study Report *Rethinking Race and Ethnicity in Biomedical Research* (2024).

The study was sponsored by the Doris Duke Foundation and the Burroughs Wellcome Fund. Any opinions, findings, conclusions, or recommendations expressed in this publication do not necessarily reflect the views of any organization or agency that provided support for the project. Copies of the Consensus Study Report are available from the National Academies Press, (800) 624-6242 or https://www.nap.edu/catalog/27913.

Health and Medicine Division

NATIONAL ACADEMIES *Sciences Engineering Medicine*

Rethinking Race and Ethnicity in Biomedical Research: Recommendations

Recommendation 1: At every stage throughout the biomedical research process, researchers should scrutinize, evaluate, and decide whether the use of race and ethnicity is appropriate or inappropriate. Researchers should:

- Identify how the historical or social context, including prior uses of race and ethnicity in research, affects the underlying evidence base for the question of interest;
- Use race and ethnicity in ethical ways based on the context and research question, with a principled scientific rationale documented throughout the study;
- Understand distinct contexts and requirements for partnering with specific populations and communities, which could include American Indian or Alaska Native Tribes and their distinct political status as sovereign nations;
- Consider the benefits of collecting race and ethnicity information for research purposes, including promoting diverse representation and equity, when these constructs are not central to the research question;
- Refrain from making unsupported inferences from the analysis, such as relying on race and ethnicity as causal attributes that drive biomedical research outcomes in individuals; and
- Weigh the potential implications, limitations, benefits, or harms of using or not using race and ethnicity.

In publications, researchers should articulate their decisions about whether and how to use race and ethnicity in their research studies and reflect on the outcomes.

Recommendation 2: Whether conducting primary research or secondary data analysis, biomedical researchers should provide an operational definition of race and ethnicity, if used, in all grant applications, manuscripts, and related products. Within these products, researchers should explain their rationale and the limitations of their approach as well as describe attributes of data provenance, such as:

- Which race and ethnicity categories were used for enrollment and/or scientific analyses and why (e.g., which version of the Office of Management and Budget categories was used);
- How race and ethnicity data were reported (e.g., self-identified or socially assigned);
- When data were collected;
- Whether any subcategories were aggregated, including whether samples were relabeled, combined, or harmonized across various sources;
- Whether any race and ethnicity data were derived (e.g., imputation, estimation), and how; and
- Whether bias may exist due to the way categories were defined and handled (e.g., sampling, classification, method of data collection, completeness of data).

Recommendation 3: Researchers should operate with transparency at every stage in the development, application, and evaluation of biomedical technology that may influence health (e.g., clinical algorithms, artificial intelligence [AI] models and tools, medical devices). Researchers should assess and report the performance of biomedical technology across a range of racial and ethnic groups.

Recommendation 4: Researchers should strive to identify which concepts often conflated with race or ethnicity (e.g., environmental, economic, behavioral, and social factors, including those related to racism) are relevant to their study. Based on those concepts, researchers should select applicable measures and do the following:

- Researchers should not rely solely on self-identification with OMB race and ethnicity categories.
- To the greatest extent possible, researchers should incorporate multiple measures in study design, data collection, and analysis to allow for comparison or combination.

- If using a single measure, researchers should articulate a clear scientific justification for why it was chosen and discuss its limitations.

Recommendation 5: At each stage of the research process, all racial or ethnic category inclusions and exclusions should be based on a clear scientific rationale motivated by the research question.

Researchers should:

- Consider oversampling for smaller populations to ensure adequate power for analysis.
- Describe and characterize all recruited populations, even if some cases cannot be included in an analysis due to limits of small sample size.
- Articulate the purpose of aggregating categories, deriving missing data, or omitting cases.
- Use aggregate category labels that are motivated by the research question (e.g., "Members of minoritized racial and ethnic groups") or reflect the analytical approach (e.g., "Remaining participants").
- Justify the choice of reference population.

Researchers should not:

- Combine categories solely to improve statistical power.
- Make inferences about residual categories.
- Aggregate participants into the nonspecific category labels "Other" or "non-White" because they can be isolating and reinforce one category as the norm.

Recommendation 6: Researchers should consider the inclusion and analysis of multiracial and multiethnic participants at each stage of the research process, especially when developing research questions and designing the study.

Throughout the course of a study, researchers should:

- Identify relevant concepts (e.g., ancestry, self-identification);
- Ensure that respondents can select multiple races, ethnicities, or ancestries during data collection;
- Report granular data for multiracial or multiethnic respondents to the greatest extent possible, while respecting confidentiality concerns; and

- Identify a plausible classification scheme for including multiracial and multiethnic people in analysis, based on the research question or context; or provide a comparison of results using alternate approaches.

Recommendation 7: Researchers collecting and using race and ethnicity data in biomedical research with human populations should identify and partner with specific communities relevant to the research context. Researchers should collaborate with community engagement experts and organizations and, to the greatest extent possible, partner directly with community members to optimize authentic, continuous, and sustained researcher–community member engagement undergirded by mutual trust.

- From the earliest stages of the project, these partnerships should be established to inform hypothesis development and study design, including how race and ethnicity information should be collected and used, through results interpretation and dissemination.
- Research teams should communicate potential benefits to community partners from project initiation through results dissemination.
- In the case of secondary data use, researchers should consult documentation or original investigators from participating studies to understand how communities were involved in the process.

Recommendation 8: Funders, sponsors, publishers, and editors of biomedical research should provide consistent guidelines to assist researchers in developing and examining their work and to promote the thoughtful use of race, ethnicity, and related concepts to enhance adoption of these recommendations.

- Journal publishers and editors, research funders, and sponsors should require researchers to provide a scientific rationale for their use of race and ethnicity, describe data provenance, and acknowledge limitations of their use.
- Journal editors and funding agencies should provide reviewers with specific guidelines for reporting race and ethnicity that should be used to assess publication and funding decisions.

- Funders of research to develop health technologies should require researchers to report results across racial and ethnic groups and encourage researchers to provide datasets, algorithms, and code in an open-source format to the greatest extent possible.

Funders, sponsors, publishers, and editors of biomedical research should periodically evaluate their policies on the use of race and ethnicity to assess the extent to which the policies are followed and upheld, monitor progress, consider the need for updates, and ensure the guidelines reflect current best practices.

Recommendation 9: To support partnerships between communities and research teams, funders and sponsors should require as appropriate a community engagement plan as part of the application. Funders should provide resources and timelines that encourage researchers to build and sustain collaborations. Research institutions, medical centers, and other biomedical research organizations should develop and support lasting, equitable relationships with community partners.

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Rethinking Race and Ethnicity in Biomedical Research

Community Engagement

A committee of the National Academies of Sciences, Engineering, and Medicine assessed the use of race and ethnicity in biomedical research across the United States. The resulting report, *Rethinking Race and Ethnicity in Biomedical Research*, presents recommendations to guide researchers and the scientific community in various areas, including community engagement.

Collaborative decision making throughout the research process is critical for improving the use of race and ethnicity in research because these concepts are interwoven with identity, social context, environmental exposures, and health. For this reason, the committee sought out community perspectives when conducting its work and developed specific conclusions and recommendations to help researchers build and maintain effective community partnerships when conducting biomedical research that collects race and ethnicity data.

DEFINING COMMUNITY ENGAGEMENT

Community engagement can be defined as "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people."[1]

Community engagement exists on a continuum. On one end of the engagement spectrum, communication is primarily unidirectional with communities informed about current research and results. In the middle of the spectrum, engagement transitions toward bidirectional communication, and communities are engaged in important, but limited, research processes, such as recruiting research participants. On the other end is shared leadership, which consists of joint decision-making and equal involvement of community partners and researchers.

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[1] CDC (Centers for Disease Control and Prevention). 1997. *Principles of community engagement, 1st ed.* Atlanta, GA: Centers for Disease Control and Prevention, p. 9.

STRATEGIES TO ENGAGE WITH COMMUNITIES

Community members can contribute to designing study protocols, including procedures for collection and use of race and ethnicity data, identifying and prioritizing research questions that are important to specific populations, providing insight and networks to aid dissemination of research results, and translating research findings into practice and policy.

The type of engagement best suited to a study will depend on the type of study, line of scientific inquiry, and community context. When planning studies, researchers should account for the time, resources, and expertise required for authentic, sustained engagement.

Research teams may need a community engagement expert who can facilitate meetings between community leaders and research team members, identify challenges, develop strategies for building trust and respect, develop an engagement or partnership plan, manage that plan, and handle logistics.

Learn more and access the full report at nationalacademies.org/race-in-biomed.

NATIONAL ACADEMIES Sciences Engineering Medicine

Rethinking Race and Ethnicity in Biomedical Research

Clinical Algorithms and the Role of AI

A committee of the National Academies of Sciences, Engineering, and Medicine assessed the use of race and ethnicity in biomedical research across the United States. The resulting report, *Rethinking Race and Ethnicity in Biomedical Research*, presents recommendations to guide researchers and the scientific community in various areas, including the development and use of clinical algorithms.

The rationale to include race and ethnicity as input variables in clinical algorithms—mathematical formulas, prediction models, or regression equations that assess multiple input variables to discern an outcome probability—is often motivated by observed differences in prevalence or clinical outcomes between racial and ethnic groups in the studies that developed these algorithms. Traditional statistical methods (e.g., regression analysis) inform most of the algorithms that clinical investigators currently employ; however, novel algorithms via artificial intelligence (AI) are showing promise in emergency triage, medical imagery, evaluating treatment options, and more.

CHALLENGES

Race and ethnicity are social variables that are inconsistently measured and have no biological basis. Their relationship to clinical outcomes is indirect and ambiguous. As such, extrapolating group-level differences to determine an individual's risk is misguided.

Datasets used to develop clinical algorithms can include race and ethnicity data and are subject to limitations of missing data, inaccuracy, and bias. There is a growing concern about how these tools could encode and perpetuate bias in underlying datasets and exacerbate existing inequities in the health care system.

Efforts to employ clinical algorithms in a way that maximizes benefits and reduces potential harms are hampered by the need for more guidance on the development, assessment, and implementation of these tools. There are some reporting guidelines for AI-enabled medical algorithms (e.g., SPIRIT-AI, CONSORT-AI), but the committee concluded that commentary on the use of race and ethnicity is limited among those guidelines (See **Chapter 4** in the report).

AI methods can detect complex patterns and relationships in the data that may not be apparent to humans. This can be helpful for analyzing large, complex datasets, but the relationships that inform the AI model are often unclear to researchers. In addition, a lack of access to an algorithm's training data and detailed methodology limits performance analysis.

STRATEGIES FOR IMPROVEMENT

Researchers should carefully consider the provenance of their data; assess any potential sources of bias; describe limitations (see **Recommendation 2**); operate with transparency in the development of biomedical technology, including AI-enabled clinical algorithms; and report performance across a range of racial and ethnic groups (see **Recommendation 3**). Algorithmic biases sometimes stem from a lack of understanding of domain-specific clinical and social aspects. One solution is to enhance statistical and AI expertise with social science, health disparities, and clinical expertise to bring a multidisciplinary approach to algorithmic development.

Learn more and access the full report at nationalacademies.org/race-in-biomed.

Rethinking Race and Ethnicity in Biomedical Research

Funders and Sponsors of Biomedical Research

A committee of the National Academies of Sciences, Engineering, and Medicine assessed the use of the social constructs of race and ethnicity in biomedical research. The resulting report, *Rethinking Race and Ethnicity in Biomedical Research*, presents recommendations to guide researchers and the scientific community in deciding if, when, and how to use race and ethnicity in biomedical research.

The report calls for researchers to take a thoughtful approach to using race and ethnicity—for example, by considering issues of race and ethnicity from the earliest stages of study design and evaluating whether variables other than race and ethnicity could better address scientific aims. The report also calls for funders and sponsors of biomedical research to help cultivate intentionality, ensure accountability, and catalyze change for the better. The following recommendations outline key areas of action for funders and sponsors of biomedical research.

DEVELOP AND UPDATE POLICIES ON USING RACE AND ETHNICITY

The report recommends funders require researchers to articulate their rationale and approaches for the use of race and ethnicity to ensure they are accountable for considering how these concepts are used in their studies. Distinguishing between uses of race and ethnicity for recruiting diverse groups of research participants and for scientific analysis in grant and funding proposals can increase transparency and scientific validity. In addition, it is important not only to have policies on the use of race and ethnicity, but also to evaluate them to ensure they are current and effective.

Recommendation 8: Funders, sponsors, publishers, and editors of biomedical research should provide consistent guidelines to assist researchers in developing and examining their work and to promote the thoughtful use of race, ethnicity, and related concepts to enhance adoption of these recommendations.

- **Journal publishers and editors, research funders, and sponsors should require researchers to provide a scientific rationale for their use of race and ethnicity, describe data provenance, and acknowledge limitations of their use.**
- **Journal editors and funding agencies should provide reviewers with specific guidelines for reporting race and ethnicity that should be used to assess publication and funding decisions.**
- **Funders of research to develop health technologies should require researchers to report results across racial and ethnic groups and encourage researchers to provide datasets, algorithms, and code in an open-source format to the greatest extent possible.**

Funders, sponsors, publishers, and editors of biomedical research should periodically evaluate their policies on the use of race and ethnicity to assess the extent to which the policies are followed and upheld, monitor progress, consider the need for updates, and ensure the guidelines reflect current best practices.

SUPPORT COMMUNITY ENGAGEMENT AND PARTNERSHIP

The report recommends that researchers collecting race and ethnicity data should collaborate and partner with community engagement experts and community members to build sustainable engagement and trust. For researchers to build relationships and do the necessary community engagement described in the report, funders need to recognize the increased time and resources it takes to engage and build lasting relationships with racial and ethnic communities to conduct research that is informed by and important to communities.

Federal research awards typically are for a period of 3 to 5 years, which is meant to encompass all aspects of the research life cycle. However, the committee concluded that funding timelines often do not account for, and are thus misaligned with, the time required for outreach to and partnership with different racial and ethnic populations for participation in research. Reservation-based research, for example, requires longer timelines for approvals to navigate the unique legal and political status of Tribal nations.

Recommendation 9: To support partnerships between communities and research teams, funders and sponsors should require as appropriate a community engagement plan as part of the application. Funders should provide resources and timelines that encourage researchers to build and sustain collaborations. Research institutions, medical centers, and other biomedical research organizations should develop and support lasting, equitable relationships with community partners.

ADDITIONAL AREAS FOR ACTION

Raise awareness. In addition to these recommendations, funders can raise awareness of these issues among the scientific community. For example, funders of biomedical research can host workshops and conferences to address considerations for using race and ethnicity, discuss challenges, share ideas, and highlight examples of successful approaches. Funders could also incorporate material from this report into available or required training opportunities. For example, key messages of this report could be incorporated into responsible conduct of research (RCR) training, which is a required course for all National Institutes of Health (NIH) intramural investigators and for all trainees on an NIH institutional research training grant or fellowship. RCR courses include instruction on proper data acquisition and ethical data use, which could include the principles outlined in this report on appropriate collection and use of race and ethnicity data.

Recognize and address evidence gaps. Moving forward starts with recognizing and acknowledging assumptions, biases, and flaws in the existing evidence. The committee concluded that the biomedical research enterprise has long emphasized race at the expense of exploring other concepts, such as racism and discrimination that are known to have more direct effects on health. Much of the existing evidence base in biomedical research has deep-rooted bias and requires reexamination. Rebuilding the evidence to examine the role of racism and other associated concepts beyond race and ethnicity categories will require investment from funders and sponsors of biomedical research.

GOING FORWARD

This report offers ways to change how race and ethnicity are used, analyzed, and reported in biomedical research. When implemented, these changes have the potential to improve the scientific rigor of biomedical research, mitigate bias that continues to affect research and health care, and build lasting trust among researchers and racial and ethnic communities. Addressing the complex issues inherent in how to use race and ethnicity thoughtfully in biomedical research will require sustained, in-depth conversations across disciplines and sectors.

Learn more and access the full report at nationalacademies.org/race-in-biomed.

Health and Medicine Division

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Helpful Resources

- Rethinking Race and Ethnicity in Biomedical Research (2024) – Full Report: https://nap.nationalacademies.org/catalog/27913/rethinking-race-and-ethnicity-in-biomedical-research

- Report Summary: https://nap.nationalacademies.org/read/27913/chapter/2

- Interactive Webpage: https://nap.nationalacademies.org/resource/27913/interactive/

- Report Highlights: https://nap.nationalacademies.org/resource/27913/Highlights_Race_in_Biomed.pdf

- Report Release Webinar Recording: https://www.nationalacademies.org/event/43893_10-2024_the-use-of-race-and-ethnicity-in-biomedical-research-report-release-webinar

- Action Guide for Funders and Sponsors of Biomedical Research: https://nap.nationalacademies.org/resource/27913/Funders_Action_Guide_Race_in_Biomed.pdf

- Action Guide for Journals and Professional Societies: https://nap.nationalacademies.org/resource/27913/Journals_Action_Guide_Race_in_Biomed.pdf

- One-pager about Community Engagement: https://nap.nationalacademies.org/resource/27913/Community_Engagement_One_Pager_Race_in_Biomed.pdf

- One-pager about Clinical Algorithms and AI: https://nap.nationalacademies.org/resource/27913/Algorithms_and_AI_One_Pager_Race_in_Biomed.pdf