



April 9, 2021

Francis Collins, MD, PhD
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Re: NOT-OD-21-066, Request for Information (RFI): Inviting Comments and Suggestions to Advance and Strengthen Racial Equity, Diversity, and Inclusion in the Biomedical Research Workforce and Advance Health Disparities and Health Equity Research

Filed electronically at grants.nih.gov.

Dear Director Collins:

On behalf of the Cystic Fibrosis Foundation, I am writing to provide comments on National Institute of Health (NIH) request for information titled *Inviting Comments and Suggestions to Advance and Strengthen Racial Equity, Diversity, and Inclusion in Biomedical Research and Advance Health Disparities and Health Equity Research*. We appreciate this opportunity to share the Foundation's thoughts on this topic and commend the NIH for requesting actionable advice on practices that the institutes can implement to support a more diverse and inclusive research workforce.

Addressing the systemic barriers that impact people of color's participation in the biomedical research workforce will require ongoing efforts from stakeholders across the research space. While we cannot address all the challenges and opportunities in these comments, we hope the insights shared below will add to the NIH's understanding of how to tackle the complex challenges that lie ahead.

Background on Cystic Fibrosis and the CF Foundation

The Cystic Fibrosis Foundation is a national organization actively engaged in the research and development of new therapies for cystic fibrosis (CF) – a rare genetic disease that affects more than 30,000 people in the United States. The CF Foundation has been engaged in virtually every element of the research and development process. The Foundation's Therapeutics Development Network (TDN) is the largest CF clinical trials network in the world. The TDN consists of 92 clinical research centers across the US and supported more than 60 multicenter trials in 2018 alone.

Cystic fibrosis affects many people of different racial and ethnic backgrounds. However, for many years there has not been adequate representation of people of color shared in the stories and descriptions of the disease by medical and public health entities, as well as by the CF Foundation and the CF community. Improving the representation of people of color within the CF community – including those in the CF research workforce – and addressing health disparities that exist within these groups is critical to the Foundation's mission of serving all people with CF.

Misperceptions of CF and Race Impact Patients, Clinicians, and Researchers

Race shapes every aspect of a patient's experience of CF. CF has historically been described as a Caucasian or white disease in literature. This perception of CF continues to be widespread; one recent survey found that over half of state department of health websites in the U.S. refer to CF as a Caucasian disease.¹ However, as of 2019, nearly five percent of people with CF in the U.S. identify as Black and nearly ten percent identify as Hispanic.² Ongoing research is breaking down the fallacy that CF is exclusively a white disease. In fact, descriptions of CF in non-Caucasian regions like sub-Saharan Africa, Pakistan, the Middle East, and Central and South America is confirming sizable CF populations independent of white heritage.^{3,4,5,6} Misperceptions of CF as a disease that impacts only those who are white is harmful to people of color with CF and can impact everything from diagnosis and access to information on the disease to quality and delivery of medical treatment and overall health.

Inaccurate perceptions of CF and race also create substantial barriers to increasing the diversity of CF clinical trial participants. For example, people of color with CF may not be approached for clinical trial opportunities for any number of reasons including a lack of cultural competency impacting relationships between research staff and potential research subjects, implicit bias impacting expectations of a patient's interest in clinical trials, or even an expectation that patients may not meet clinical trial inclusion criteria that has failed to account for differences in normal ranges for standard lab tests between people of color and their white peers. In 29 CF studies that reported race and ethnicity over a period of nearly 15 years, Hispanic and Black people with CF made up only two percent and one percent of participants, respectively. Making clinical trial design and engagement more inclusive of people of color with CF will be critical for improving treatment options and health outcomes for these groups; Black and Hispanic people with CF account for nearly 40 percent of individuals with rare mutations that are not candidates for available treatments addressing the underlying cause of the disease.

Improving diversity of the CF research workforce is a necessary component of ensuring better engagement and support of people of color with CF in clinical trials as well. Much work remains in tackling systemic issues impacting diversity of the CF and broader research workforce. For the CF research field, the mischaracterization of CF as a disease that only impacts white people can also dissuade researchers from diverse backgrounds from entering the CF research workforce and leads to a dearth of role models for researchers of color who may otherwise consider entering this field.

These interconnected and systemic issues play an outsized role in creating barriers to people of color entering and staying in the biomedical research workforce. However, there are a number of strategies

¹ https://www.youtube.com/watch?v=GVqA-SET9_M&list=PLhoQ6vyZhggqFW-h_VcTBb1WMuFs3UIWW&index=11

² <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2019-Patient-Registry-Annual-Data-Report.pdf>

³ Aziz DA, Billoo AG, Qureshi A, Khalid M, Kirmani S. Clinical and laboratory profile of children with Cystic Fibrosis: Experience of a tertiary care center in Pakistan. *Pak J Med Sci.* 2017 May-Jun;33(3):554-559. doi: 10.12669/pjms.333.12188. PMID: 28811770; PMCID: PMC5510102.

⁴ Mayer Lacrosniere S, Gerardin M, Clainche-Viala LL, Houdouin V. Phenotypic Presentations of Cystic Fibrosis in Children of African Descent. *Genes (Basel).* 2021 Mar 23;12(3):458. doi: 10.3390/genes12030458. PMID: 33807078; PMCID: PMC8004676.

⁵ Puppo H, Von Oetinger A, Benz E, Torres-Castro R, Zagolín M, Boza ML, Astorga L, Bozzo R, Jorquera P, Kogan R, Perillán J. Caracterización de la capacidad física en niños del Programa Nacional de Fibrosis Quística de Chile [Characterization of the physical capacity in children of the Chilean National Program of Cystic Fibrosis]. *Rev Chil Pediatr.* 2018 Oct;89(5):638-643. Spanish. doi: 10.4067/S0370-41062018005000812. PMID: 30571807.

⁶ Bustamante AE, Fernández LT, Rivas LC, Mercado-Longoria R. Disparities in cystic fibrosis survival in Mexico: Impact of socioeconomic status. *Pediatr Pulmonol.* 2021 Mar 3. doi: 10.1002/ppul.25351. Epub ahead of print. PMID: 33656284.

NIH and other stakeholders can consider to increase the awareness, interest, opportunities, and ultimately access to entry into the research workforce for people of color.

Addressing Barriers for Entering the Biomedical Research Workforce

Lack of exposure to biomedical research as a potential career path, as well as a lack of diverse role models in the research field, can significantly hamper research workforce diversity. Increasing opportunities for students of color at all ages to learn about biomedical research and exposing students to diverse role models whose background and experiences reflect theirs can help increase interest in scientific and research field. Strategies for increasing exposure to and interest in the research field could additionally include increasing resources for STEM studies in underserved areas, collaborating with historically Black colleges and universities (HBCUs) to highlight opportunities, focusing on minority-centered conferences for recruitment, and improving access to scholarship and internship opportunities for people of color.

A hostile academic environment for people of color, which can manifest as both overt and covert racism and bias, can also lead to disproportionate attrition from the field. An important step in increasing the diversity of the research workforce is acknowledging the role that systemic and institutional bias plays in impacting representation in the workforce. Additionally, bias training can play a role in improving the academic environment, but it should not supplant needed systemic or organizational changes. Academic institutions should do outreach to people of color to narrow gaps in understanding of how the system is experienced by these groups and what steps are needed to ensure academic success.

Addressing Institutional Culture and Supporting Mentorship

Race impacts career development, advancement, and mentoring to a significant degree. While many efforts to increase diversity in the sciences focus on attracting people of color to the research space, more needs to be done to create a supportive and culturally competent work environment in order to better serve those already in the workforce.

Academic institutions must foster a culture that celebrates diversity and inclusion while ensuring accountability. Cultural changes such as signaling intolerance of both macro and microaggressions and having a trusted process for taking action against bigotry in the workplace are needed to improve retention of people of color in the research workforce. Advocates for research workforce diversity, including leaders at institutions, educators, and researchers, can play an important role in supporting and encouraging the career development and progression of people of color in the research field. Leaders at research institutions should ensure sufficient time and financial investments are dedicated to implement programs such as necessary training to support organizational change. Additionally, policies and guidelines for research grant recipients should require training and ongoing education regarding implicit bias and equity in the workplace.

Research funding is critical to career advancement as well, and steps should be taken to improve funding access for people of color in the research workforce at all training and career stages. Required bias training for grant review committee members may alleviate some of the impacts of racial bias on the funding process. Grant makers should consider additional measures to reduce bias such as blinding grant reviews by removing references to names or other indicators that may inappropriately impact grant reviewers' ratings of an application. Adequate research infrastructure is also essential for supporting research efforts, and funding opportunities are needed to ensure that people of color in the research field are able to access the necessary equipment and resources to carry out research activities regardless of how well-resourced their academic institution is.

While making individual grants more accessible to researchers of color is an important step, offering multiyear programs tailored to support researchers of color at critical career stages, such as those who are new principal investigators, can help get researchers past some of the more onerous barriers to career advancement. Mentorships can also play a critical role in academic success and career advancement in the biomedical research space. Both formal and informal mentorships can help spark trainee interest in an area of research, expose trainees to career paths where they feel they can pursue meaningful work, and provide support through different career stages. However, a dearth of mentors from diverse backgrounds can impact interest in research careers as well as opportunities for career advancement for people of color.

The benefits of mentorship for people of color in a field with limited diversity can be even more critical to career success. Mentorships for people of color can provide important support such as creating a space for individuals to build confidence in their professional capabilities, learn how to navigate career advancement in their field, and receive guidance from a trusted and experienced career professional. Mentoring and other career support or advancement programs that create spaces for people of color in the research workforce to support one another can help fill this need. People of color should be encouraged to pursue formal and informal mentorships, and to become mentors themselves.

Addressing Gaps in Health Disparities and Inequities Research

Health disparities and inequities research can be advanced through better engagement of people of color in the research process. Engaging different communities in research prioritization and study design can ensure that research is focusing on the most important issues identified by those communities and that studies are designed in ways that are respectful for people experiencing disparities.

Researchers should undergo training on how to best engage people experiencing disparities in research, including how to build trust with communities that have historically been harmed by research or experienced discrimination from the healthcare system. Additionally, institutions and grant makers could require research proposals to explicitly address how they will support inclusion of diverse participants, including plans for building trust with community members and ensure adequate recruitment of people from diverse backgrounds. Ensuring adequate patient representation on committees and approval boards, including Institutional Review Boards, can ensure that diverse patient needs are considered throughout the research process.

Real world research (RWR) has the potential to remove barriers to research participation as well—for instance by relying on mobile or home monitoring devices to collect data—and may help increase opportunities for individuals from underrepresented populations to participate in studies. Further investments in the development and validation of RWR study designs and analytic methods are needed to advance the use of RWR. Grant reviewers must be encouraged to consider studies employing appropriate RWR methods.

Additionally, there are several gaps in research currently that should be addressed. Of note, more research is needed to understand how lack of trust in the medical community by people of color due to historical and ongoing racial bias impacts their full participation in care. Research is needed to explore and better define what normal laboratory values are for people of color, as these definitions often impact whether a person of color is included or excluded from clinical trials. Finally, research teams require training to more effectively engage communities of color in research projects. The NIH could sponsor valuable programs that ultimately advance participation of communities of color in all facets of the research enterprise.

We are encouraged by the NIH's efforts to address the impacts of systemic racism on the biomedical research enterprise. We recognize that these are enormous challenges that will require concerted effort from stakeholders across the biomedical research world to address. There are important opportunities for collaboration on these complex challenges, and we encourage the NIH to foster ongoing dialogue with patient and research communities as you continue to tackle these issues.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mary B. Dwight', written in a cursive style.

Mary B. Dwight

Chief Policy and Advocacy Officer
Senior Vice President of Policy and Advocacy
Cystic Fibrosis Foundation