

April 23, 2021

Francis Collins, MD, Ph.D.
Director
National Institutes of Health
31 Center Drive
Bethesda, MD 20815
RE: Notice No. NOT-OD-21-066

Dear Dr. Collins:

On behalf of the American Thoracic Society (ATS), thank you for your efforts to promote equity and diversity in the U.S. biomedical research workforce and advance health disparities research. We believe the new UNITE initiative provides a solid framework to guide these efforts. We look forward to working with you and the leadership of all NIH institutes on development of this and other important NIH efforts to promote equity, diversity, and inclusion. We have the following comments:

The ATS applauds the efforts of the NHLBI in promoting racial equity and diversity in the biomedical workforce and health disparities. The NHLBI has held workshops, webinars, and other collaborative activities with the ATS, and the heart, lung, blood, and sleep communities focused on minority scientist recruitment and retention. The NIMHD/NHLBI Community Engagement Alliance (CEAL) program, is addressing COVID-19 disparities by educating minority communities across eleven states about disease prevention practices and working to improve confidence and uptake of COVID vaccines and treatments. Other pioneering NHLBI studies that are advancing health equity research include the Disparities Elimination Through Coordinated Interventions to Prevent, Control Heart and Lung Disease Risk (DeCIPHER) program, Consortium on Asthma among African-Ancestry Populations in the Americas (CAAPA), and the NHLBI/NIMHD funded Hispanic Community Health Study/Study of Latinos (HCHS/SOL).

Biomedical Research Workforce

In June 2015, the NHLBI Division of Lung Diseases (DLD) hosted the *Training for a Diverse Biomedical Workforce Workshop*, to (1) assess the effectiveness of the current NHLBI diversity program, (2) improve its strategies towards achieving its goal, and (3) provide guidance to assist the transition of diversity supplement recipients to independent NIH grant support. The workshop report, published in the *Annals of the ATS* in April 2016 ([DOI: 10.1513/AnnalsATS.201509-624OT](https://doi.org/10.1513/AnnalsATS.201509-624OT)), identified key socio-economic barriers to success for

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diverse research scientists, including low salaries, lack of salary adjustments to compensate for high cost of living areas, lack of child care and supports including paid parental leave for working parents. ⁱ It recommended a series of financial support mechanisms related to cost of living and family support and targeted mechanisms for securing extramural funding and external mentors to promote diversity in the workforce. These included:

- Adjustment of stipends based on regional cost of living, loan repayment assistance and institutional support for trainees with families
- Childcare supplements for postdocs, maternity or parental leave support from university/mentor and flexibility in work hours
- Accountability of universities to retain minority faculty, reflected in NIH funding decisions
- Meetings/webinars for grant-writing forums, more transparent guidelines for writing successful grants
- Coordination assistance from NIH/NHLBI to ensure that diversity supplement/fellowship awardees find and maintain a relationship with a mentor other than primary investigator, mentor/coach system with additional peer mentoring

The ATS urges the NIH to utilize the recommendations from this workshop to pursue policy changes to advance diversity and inclusion across the biomedical research enterprise. We recommend that all NIH institutes convene individual workshops to identify barriers to recruiting and retaining a diverse workforce and develop strategic plans for implementing recommendations.

Expand Support for Research Training and Incentivize Mentoring

As identified in the NHLBI DLD workshop report, the ATS recommends that the NIH develop additional mechanisms for supporting research training, including ways to incentivize mentors. Mentor incentives are not currently incorporated in most NIH training grants, and we believe the lack of these mechanisms is a barrier to training and mentoring that may contribute to the underrepresentation of racial and ethnic groups. The NIH BUILD and FIRST COHORT programs provide such support, and we urge the NIH to expand these programs and use them as models for development of other programs and initiatives to support training, mentoring, and career path advancement for racial and ethnic minorities. In addition, the ATS recommends expansion of the NIH Culture for Change program, which supports URM's build and advance their career path.

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Elevate the Recruitment and Retention Plan to Enhance Diversity to Scorable Status

In November 2020, the ATS wrote to Michael Lauer, M.D., NIH Deputy Director for Extramural Research, requesting that the NIH take additional steps to improve the participation of under-represented minorities (URM)'s and people with disabilities in the research workforce. Specifically, the ATS recommended the elevation of the Recruitment and Retention Plan to Enhance Diversity to scorable status for all new and renewal Institutional Training Grant applications (T32, T35, K-level) across all NIH Institutes and Centers. In addition, we recommend that NIH extend the Plan to include diversity among training grant program faculty trainers (mentors) as a review criterion across all NIH Institutes and Centers. The ATS believes that scoring these plans will help recognize programs that have developed and successfully implemented effective plans to recruit and retain URM scientists. More importantly, scoring these plans will provide programs that have been less successful in recruiting and retaining URM scientists with the needed additional incentive to change current practices to ensure that their efforts to recruit, develop and retain URM scientists are a priority.

NIH Loan Repayment Programs

The ATS is concerned that NIH loan repayment success rates for racial and ethnic minorities are currently very low, particularly for African American and Latino applicants. Loan repayment is an essential support mechanism for many racial and ethnic minority researchers and students who come from low socio-economic backgrounds. Without access to loan repayment, recruitment and retention for many minority scientists will continue to be stifled. The ATS urges the NIH to restructure and expand current loan repayment programs to ensure that this vital financial support for early-career scientists from racial and ethnic minorities is available.

NIH Study Section URM Representation and Reviewer Bias Training

The ATS recommends that the NIH prioritize minority representation on NIH study section panels. In addition, we recommend that the NIH consider programs to enhance study section panel member training on racial bias, diversity, and inclusion. While such training currently exists, we believe it should be enhanced. Reviewers should ask whether the proposed study includes a representative sample of the population disproportionately burdened by the disease of interest. To ensure successful accrual of representative samples, reviewers need to also assess minority inclusion plans and outreach initiatives, considering these when evaluating the scientific merit of the application and overall scoring.

Diversity and Inclusion in Research Support and Administrative Staff

We note that the NIH RFI background states that recruitment, training, and advancement apply equally to support administrative staff that sustains the research enterprise. The ATS urges the

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NIH to develop specific policies, procedures, and initiatives to promote diversity and inclusion for scientific research administrative, laboratory and other support staff.

Research Areas – Significant Gaps to Expanding Health Disparity/Health Equity Research

In order to effectively advance health disparities and health equity research, the ATS firmly believes that there must be an expansion of research in these areas across all NIH institutes through intramural and extramural divisions. The COVID-19 pandemic and its disproportionate impact on racial and ethnic minorities has clearly illustrated the needs. We urge the NIH to begin the expansion of health disparities and health equity research immediately, including through specific funding opportunities and other mechanisms. This includes expansion of both participation of minorities in research studies and community engagement initiatives, and policies and procedures to promote engagement of racial and ethnic minority communities that have historically been excluded. The NIEHS's Partnerships for Environmental Public Health (PEPH) is a model program in this area.

URM in Clinical Trials

While we applaud the NIH for its recent efforts to expand URM representation in research, including the creation of the 30% target for URM in clinical trials, there is much more that should be done in this area. Although updated NIH Policy now requires NIH-defined Phase III clinical trials to include valid analyses by sex/gender and race/ethnicity to be reported in clinicaltrials.gov, compliance with population composition does not ensure the ability to perform meaningful subgroup analysis for the majority of clinical trials with small sample size.ⁱⁱ This policy also does not extend to other types of clinical research, including device trials, trials at other stages of the FDA process, or observational studies. The ATS recommends that the NIH encourage the enrollment of URM in clinical trials across age and gender groups with amended language in RFA's and PAR's and that these policies be standardized across all NIH institutes and centers and include processes to train scientific review and program officers. Similarly, when scientifically appropriate, the enrollment of URM with specific genetic predispositions should be given the opportunity to participate in clinical trials. Additional support for clinical research staff including translators and community liaisons should be encouraged to optimize URM participation.

Specific Health Equity Research Areas - Pulmonary Function Testing

Current guidelines for interpretation of pulmonary function tests recommend the use of race/ethnicity-specific reference equations (spirometry) or race/ethnicity adjustments (for other measurements). However, there are many unanswered questions about the suitability of using race/ethnicity-specific reference equations. Recent high-profile media coverage drawing

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from troubling historical anecdotes have raised concerns about the potential for race-based medicine to propagate racial/ethnic disparities. Current practice in pulmonary medicine includes the use of race-specific lung function prediction equations. However, there is increasing concern that the use of race and ethnicity in the interpretation of pulmonary function tests is intertwined with structural racism and might contribute to health disparities. Further, this practice may contribute to racial disparities by treating pathological lung function decrements as normal race-specific variation.

The ATS is working to review the effect of such race-based interpretations and implications for research and clinical care. The ATS urges the NIH to fund research into the consequences of this practice and to explore alternatives as we reconsider the use of race and ethnicity in lung function prediction equations. Additionally, the ATS recommends that the NIH and other government agencies fund more research on the root causes and solutions to racial/ethnic differences in lung function. We specifically recommend funding pediatric studies to determine the prenatal and early life influences on the development of lung function, in light of higher rates of inadequate prenatal care among minorities. Similarly, there is a clear unmet need for research and guidance concerning predicted normative values and changes overtime in PFTs of transgender individuals.

Pulse Oximetry

There has been widespread discussion, including within medical societies such as the ATS, about clinical medical procedures and devices that are inherently biased or are utilized in racially biased ways. Within pulmonary and critical care medicine, there are long-standing concerns regarding the accuracy of pulse oximetry across the spectrum of patient populations, particularly among those with darker skin color. Pulse oximetry is among the most common measures in healthcare, used either intermittently or continuously in millions of acutely and critically ill patients each year. Accurate measurement of arterial blood oxygen saturation via pulse oximetry is vital to the clinical management of patients. The universal use of these devices and the need for accuracy when caring for patients in intensive care units make this both urgent and important for clinicians in critical care. The ATS is working with the FDA and sister societies to change clinical practice utilization of pulse oximeters. More research in this area would help inform and guide these efforts. The ATS recommends that the NIH support research, with the engagement of the NIMHD, to establish the range of normal oxygenation levels for all skin types and optimal utilization of the device. Furthermore, design and approval of medical devices should incorporate studies across different racial and ethnic groups to prevent additional disparities in patient monitoring.

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ATS Health Equity Initiatives

The ATS Executive Committee, together with the ATS Health Equality and Diversity Committee, are devoted to accelerated efforts to address health disparities and promote health equity, diversity, and inclusion. Such efforts have been enhanced in response to the marked racial and ethnic disparities in the COVID-19 pandemic in the U.S. We believe the following ATS Health Equity initiatives can serve as models for NIH institutes and welcome partnerships in such efforts.

In collaboration with the CHEST Foundation and our industry partners, the ATS funded 3 new grants on health disparities over the last year (e.g., a [Research Grant in Diversity](#)), while also creating a publicly available website with a video and written educational materials on COVID-19 in English and Spanish (<https://formylunghealth.com>). We targeted the most affected communities and received an excellent response, recording 2.7 million views of the educational video in the first seven weeks. Moreover, the ATS Research Program funded an unrestricted grant for under-represented minority members while the ATS continued to fund [Minority Trainee Development Scholarships](#) and a [Health Equality Fellowship](#), and the ATS Scholar published a special collection on combatting racism in health professions education. Finally, the [ATS Methods in Epidemiologic, Clinical and Operations Research \(MECOR\)](#) program continues to train researchers from low and middle-income countries, helping to support early-career scientists and build scientific research infrastructure in those countries.

The ATS appreciates the opportunity to comment. Please contact Nuala S. Moore, Director of Government Relations, with any questions at Nmoore@thoracic.org.

Sincerely,



Juan C. Celedón, MD, DrPH
President
American Thoracic Society

ⁱ Ann Am Thorac Soc Vol 13, No 4, pp 562–567, Apr 2016. DOI: 10.1513/AnnalsATS.201509-624OT

ⁱⁱ NOT-OD-18-014: Revision: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. Accessed November 25, 2020. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html>

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