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IMPLEMENTING JUSTICE IN RESEARCH: BEYOND EQUITABLE SELECTION

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Abstract

The COVID-19 pandemic and the racial reckoning following the murder of George Floyd and too many other Black and Brown people in the summer of 2020 prompted a broader public discussion of the continuing effects of systemic racism and the need for reform. Within the research community, these experiences and conversations forced a reconsideration about what the principle of justice requires and how to achieve more equitable research. This Article will argue that advancing justice in research is the responsibility of the entire research community—researchers, IRBs, public and private funders, academic institutions that educate and employ researchers, publishers, and more. The Article will start by reviewing persistent injustices in research and then will turn to how justice has been and should be conceptualized in the research context. Finally, it will consider what steps different stakeholder can take to implement justice in research that can lead to greater health equity.

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I. INTRODUCTION

Justice has long been identified as one of the core principles of research ethics,¹ yet the research community—researchers, institutional review boards (“IRBs”), funders, and scholars—have struggled to operationalize it in ways that give it as much weight as the other two core principles, respect for persons and beneficence.² Conversations about justice in research often begin and end with the enduring impact of Public Health Service’s infamous Tuskegee Syphilis Study on the representation of Black people and other people of color in research, without delving into the underlying systems that gave rise to and sustained that forty-plus year study, and continue to impact research today.³ These conversations also achieved only limited success in developing strategies for affecting long lasting change.

The COVID-19 pandemic and the racial reckoning that followed the murder of George Floyd and too many other Black and Brown people in the summer of 2020 prompted a broader public discussion of the continuing effects of systemic racism across all aspects of life and the need for reform.⁴ While everyone was vulnerable to the novel infectious agent, SARS-COV-2, the pandemic reinforced the disproportionate patterns of illness and death on low socioeconomic

1. See generally NAT’L COMM’N FOR THE PROT. OF HUM. SUBJECTS OF BIOMEDICAL & BEHAV. RSCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH (1979), https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf [hereinafter BELMONT REPORT].

2. See, e.g., Patricia A. King, *Justice, Race, and Racism in Research*, in BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH 112 (Jeffrey P. Kahn et al. eds., 2d ed. 2018); John Noel Viaña et al., *From Paternalism to Engagement: Bioethics Needs a Paradigm Shift to Address Racial Injustice During COVID-19*, 21 AM. J. BIOETHICS 96 (2021).

3. King, *supra* note 2, at 113–15.

4. See, e.g., Judy Battista, *NFL Commits \$250M Over 10-Year Period to Combat Systemic Racism*, NFL NEWS (June 11, 2020, 4:39 PM), <https://www.nfl.com/news/nfl-commits-250m-over-10-year-period-to-combat-systemic-racism>; Katie Benner, *Barr Says There Is No Systemic Racism in Policing*, N.Y. TIMES (June 8, 2020), <https://www.nytimes.com/2020/06/07/us/politics/justice-department-barr-racism-police.html>; Press Release, Patty Murray, Ranking Member, Senate HELP Comm., Senator Murray on Nationwide Protests for George Floyd (Jun. 3, 2020), <https://www.murray.senate.gov/senator-murray-on-nationwide-protests-for-george-floyd-this-is-about-the-systemic-racism-that-has-plagued-our-country-since-our-founding-and-is-not-changing-nearly-fast-enough/>; Gretchen Whitmer, *The Coronavirus Is a Civil Rights Battle, Too*, N.Y. TIMES (June 2, 2020), <https://www.nytimes.com/2020/06/02/opinion/gretchen-whitmer-coronavirus-george-floyd.html>; Jeanna Smialek, *Minneapolis Fed President Says Systemic Racism Hurts the Economy*, N.Y. TIMES (June 17, 2020), <https://www.nytimes.com/2020/06/17/business/economy/nel-kashkari-federal-reserve-racism.html>; Christine Spolar, *Data Science Proved What Pittsburgh’s Black Leaders Knew: Racial Disparities Compound Covid Risk*, KAISER HEALTH NEWS (Dec. 7, 2021), <https://kffhealthnews.org/news/article/data-science-proved-what-pittsburghs-black-leaders-knew-racial-disparities-compound-covid-risk/>; Jennifer Tsai, *COVID-19 Is Not a Story of Race, but a Record of Racism – Our Scholarship Should Reflect That Reality*, 21 AM. J. BIOETHICS 43 (2021).

communities.⁵ That these communities are more commonly comprised of historically disadvantaged, racialized minorities are traceable to policies that limited where these groups could live, their access to education and health care, and their job opportunities, among other things, that contribute to persistent disparities on multiple dimensions, including health and wealth.⁶ The callousness with which Derek Chauvin murdered George Floyd, while fellow officers watched, made it impossible for the American public to continue to ignore the well-documented disparities in how Black communities and other communities of color are treated by law enforcement compared to White communities.

Within the research community, these experiences and the important conversations surrounding them forced a reconsideration about what the principle of justice requires and what steps to take to create more equitable research.⁷ This Article will argue that advancing justice in research is the responsibility of the entire research community—researchers, IRBs, public and private funders, academic institutions that educate and employ researchers, publishers, and more. Part II will start by reviewing persistent injustices in research.⁸ Then, Part III will turn to how justice has been and should be conceptualized in the research context.⁹ Finally, Part IV will consider what steps different stakeholders can take to implement justice in research.¹⁰ It is important to recognize that the research enterprise is embedded within a society with its own justice issues that may be more pressing or that might constrain our ability

5. Latoya Hill & Samantha Artiga, *COVID-10 Cases and Deaths by Race/Ethnicity: Current Data and Changes over Time*, KFF (Aug. 22, 2022), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/covid-19-cases-and-deaths-by-race-ethnicity-current-data-and-changes-over-time/>; David R. Williams & Lisa A Cooper, *COVID-19 and Health Equity – A New Kind of “Herd Immunity,”* 323 JAMA 2478 (2020); Mark Felix, *Black Covid Long-Haulers Felt Invisible to the Health Care System, So They Formed Their Own Support Groups*, NBC NEWS (Aug. 28, 2022, 6:00 AM), <https://www.nbcnews.com/news/nbcblk/black-covid-long-haulers-felt-invisible-health-care-system-formed-supp-rcna44468>.

6. Connie L. McNeely & Laurie A. Schintler, *The Pandemic Challenge: Reflections on the Social Justice Dynamic*, 12 WORLD MED. HEALTH POL’Y 344, 345 (2020) (“Recognizing specifically disadvantaged populations and communities as particularly vulnerable to the ravages of the pandemic, related threats to public health also are translated and understood within broader struggles for social and environmental justice and human rights.”).

7. For example, Public Responsibility in Medicine & Research (“PRIM’R”), the professional organization for human research protection professionals, opened its 2021 annual Advancing Ethical Research Conference with the Plenary Session “Advancing Justice and Equity in Research – How Can Research Stakeholders Be Agents of Change?” and included an “Advancing Justice and Equity Track” with 12 separate sessions. *2021 Advancing Ethical Research Conference Agendas by Day*, PRIM&R, <https://aer-sber21.eventscribe.net/agenda.asp?BCFO=P&pfp=days&fa=&fb=&fc=&fd=&all=1&mode=> (last visited January 18, 2024). Only “A Dialogue with the Feds Track” and “IRB Operations Advanced Track” had more sessions. *Id.*

8. *See infra* Part II.

9. *See infra* Part III.

10. *See infra* Part IV.

to realize change within the research enterprise.¹¹ However, those conditions do not absolve us from the ability to seek change within the research sphere. Moreover, more equitable research could influence change within the broader society. It may also lead to improvements in other areas of ethical concern, such as consent and risk-benefit assessment, and, thus, more ethical research overall.

II. PERSISTENT INJUSTICES IN RESEARCH

Inequities pervade the research enterprise in the United States. Part II demonstrates that the benefits and burdens of research are distributed inequitably. Part II also suggests that this inequitable distribution results, in part, from inequitable representation among researchers, academic leadership, research oversight and peer review committees, and journal editors.

A. *Inequitable Representation as Research Participants*

The National Institutes of Health (“NIH”) identified several populations that are underrepresented in biomedical, clinical, behavioral, and social science research. These populations include “people with disabilities, people from disadvantaged backgrounds, and underrepresented racial and ethnic groups, such as [B]lacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders.”¹² There are multiple factors resulting in underrepresentation. A long history of abuse at the hands of medical professionals and researchers led to mistrust among Black people and other people of color that may make them reluctant to participate in research.¹³ But there is also evidence that people of color are not asked to participate in research at the same rates as White people.¹⁴ Structural factors impacting housing, insurance, and income likely also impact which populations are seen in different settings and, thus, are recruited into research.¹⁵ Explicit

11. As a specific example, during the writing of this paper, the United States Supreme Court issued its decision in *Students for Fair Admissions, Inc. v. President and Fellows of Harvard College*, 143 S. Ct. 2141 (2023) (decided jointly with *Students for Fair Admissions, Inc. v. University of North Carolina et al.*, No. 21-707), prohibiting the use of race in college admissions.

12. *Underrepresented Population*, NAT’L CTR. FOR ADVANCING TRANSLATIONAL SCI., NAT’L INSTS. OF HEALTH, <https://toolkit.ncats.nih.gov/glossary/underrepresented-population/> (last visited Dec. 14, 2023). Because the data on underrepresented minorities is more robust than for other underrepresented populations (including people living with disabilities or from LGBTQI+ communities), the Article focuses mostly on these populations. However, the arguments made for more inclusive and equitable research apply across underrepresented populations.

13. Patricia A. King & Leslie E. Wolf, *Empowering and Protecting Patients: Lessons for Physician-Assisted Suicide from the African-American Experience*, 82 MINN. L. REV. 1015, 1025–30 (1998).

14. Soumya J. Moramkam et al., *Bias and Stereotyping Among Research and Clinical Professionals: Perspectives on Minority Recruitment for Oncology Clinical Trials*, 126 CANCER 1958, 1965 (2020).

15. *Policy of Inclusion of Women in Clinical Trials*, OFF. ON WOMEN’S HEALTH, U.S. DEP’T OF HEALTH AND HUM. SERVS., <https://www.womenshealth.gov/30-achievements/04> (last visited Dec. 14, 2023).

policies also make an impact. For example, from 1977 to 1993, the Food and Drug Administration (“FDA”) recommended *excluding* women of childbearing potential in early drug studies and including them in later studies, if there were animal data demonstrating safety with respect to fetal development and female reproduction.¹⁶ The agency interpreted the term “childbearing potential” broadly, to exclude celibate women or women on effective birth control from studies.¹⁷ This system led to the predominant norm for clinical research as the White male, which created absurd results.¹⁸

When Congress enacted the NIH Revitalization Act of 1993, it included amendments to the Public Health Act that the legislators intended to encourage inclusion of both women and members of racial and ethnic minorities.¹⁹ FDA withdrew its policy excluding women of childbearing potential in 1993.²⁰ The FDA Modernization Act of 1997 then required FDA to develop guidance on inclusion of women and minorities in clinical trials.²¹ Despite these changes, underrepresentation of women and historically marginalized and minoritized populations persists.²² A recent National Academies of Sciences (“NAS”) consensus study report concluded that “[d]espite the increased focus on the lack of women and historically underrepresented populations in [United States]-based clinical trials and research, research participants remain mostly [W]hite and

16. *Id.*

17. See generally Vanessa Merton, *Impact of Current Federal Regulations on the Inclusion of Female Subjects in Clinical Studies*, in 2 WOMEN AND HEALTH RESEARCH: ETHICAL AND LEGAL ISSUES OF INCLUDING WOMEN IN CLINICAL STUDIES 65 (1994).

18. Rebecca Dresser, *Wanted: Single, White Male for Medical Research*, 22 HASTINGS CTR. REP. 24, 24 (1992) (“Most amazing is the pilot project on the impact of obesity on breast and uterine cancer conducted—you guessed it—solely on men.”). Although rare, men do develop breast cancer. *Breast Cancer in Men*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 25, 2023), <https://www.cdc.gov/cancer/breast/men/index.htm>. Only women with “a uterus” are susceptible to uterine cancer. *Basic Information about Uterine Cancer*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 14, 2023), https://www.cdc.gov/cancer/uterine/basic_info/index.htm.

19. Pub. L. No. 103-43, § 101, 107 Stat. 122, 133–35 (1993) (codified at 42 U.S.C. § 289a-2). In accordance with these amendments, NIH is required to “ensure the inclusion of women and members of racial and ethnic minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question under study.” *Inclusion of Women and Minorities as Participants in Research Involving Human Subjects*, NAT’L INSTS. OF HEALTH (Oct. 11, 2022), <https://grants.nih.gov/policy/inclusion/women-and-minorities.htm>.

20. *Gender Studies in Product Development: Historical Overview*, U.S. FOOD & DRUG ADMIN. (Feb. 16, 2018), <https://www.fda.gov/science-research/womens-health-research/gender-studies-product-development-historical-overview> [hereinafter *Gender Studies*].

21. Pub. L. No. 105-115, § 115, 111 Stat. 2296, 2313 (1997).

22. Vered Daitch et al., *Underrepresentation of Women in Randomized Controlled Trials: A Systematic Review and Meta-Analysis*, TRIALS, Dec. 21, 2022, at 3, 6 (finding a median enrollment rate of 41% rather than 50% and concluding “that women are being inadequately represented, in the selected medical fields analyzed in our study, in recent [randomized controlled trials]”); NAT’L ACADEMIES OF SCI., ENG’G, & MED., IMPROVING REPRESENTATION IN CLINICAL TRIALS AND RESEARCH: BUILDING RESEARCH EQUITY FOR WOMEN AND UNDERREPRESENTED GROUPS 35–36 (K. Bibbins-Domingo & A. Helman eds., 2022).

male.”²³ The report further noted that “[a]lthough contemporary reviews have shown increases in participation of women, and more modest increases in participation of racial and ethnic minority population groups and older populations, substantial and significant underrepresentation remains, particularly within certain medical disciplines and diseases, including cardiology, oncology, Alzheimer’s Disease and HIV/AIDS.”²⁴

These conclusions are consistent with the findings of a recent effort to develop a measure of fair inclusion of traditionally underrepresented populations in novel oncology trials. The researchers found that, for 56% of sponsors, women were enrolled in trials at rates similar to their disease prevalence, whereas this was true for only 16% of sponsors with respect to Black, Asian, Hispanic, or Latinx patients.²⁵ This underrepresentation of racial and ethnic minorities is borne out by other studies:

[f]or example, African American and Hispanic participants comprise well under 10% of the Alzheimer’s Disease Neuroimaging Initiative’s ([“]ADNI[“]) research sample in 2012 [] despite evidence of higher prevalence and incidence of [Alzheimer’s Disease (“AD”)] in these populations Equally concerning is the fact that several ethnic and racial populations, such as American Indians/Alaska Natives as well as Pacific Islanders, are frequently minimally represented (or entirely absent) in AD research.²⁶

A recent systematic review of a broader set of randomized controlled trials—including cardiovascular disease, neoplasms, endocrine system diseases, respiratory tract diseases, bacterial and fungal infections, viral diseases, digestive system diseases, and immune system diseases—found underrepresentation of women for all these diseases except immune system diseases, with a median enrollment rate of only 41%.²⁷

Such underrepresentation has real life impact. The NAS consensus study report identifies “seven potential threats” resulting from underrepresentation, two of which directly relate to this Article.²⁸ First, without adequate representation, excluded populations may not benefit from the research results. As the report describes, “[i]nitially, the results from . . . RCTs were largely considered to be generalizable to all patient populations.”²⁹ However, the report

23. NATIONAL ACADEMIES, *supra* note 22, at 35 (citations omitted).

24. *Id.* (citations omitted).

25. Tanvee Varma et al., *Metrics, Baseline Scores, and a Tool to Improve Sponsor Performance on Clinical Trial Diversity: Retrospective Cross Sectional Study*, *BMJ MEDICINE*, Jan. 5, 2023, at 4.

26. Khushnoo K. Indorewalla et al., *Modifiable Barriers for Recruitment and Retention of Older Adults Participants from Underrepresented Minorities in Alzheimer’s Disease Research*, 80 *J. ALZHEIMER’S DISEASE* 927, 932–33.

27. Daitch et al., *supra* note 22, at 4.

28. NAT’L ACADEMIES, *supra* note 22, at 23–33.

29. *Id.* at 23–25.

goes on to detail various examples demonstrating how flawed that assumption is.³⁰ Relying on a research base that leaves out large segments of the population leaves the excluded groups vulnerable to negative health effects that generate an economic cost.³¹

B. Inequitable Representation as Researchers

The problem of underrepresentation in research extends beyond research participation; researchers from historically minoritized populations are similarly underrepresented. A recent National Science Foundation funded report found that “[w]hile underrepresented minority (“URM”) students earn 21 percent of STEM Bachelor’s degrees, only 10.1 percent of STEM faculty at 4-year institutions are from URM backgrounds.”³² For context on this data, the 2020 census reported that 43.6% of the United States population would qualify as a URM.³³ Specifically, 58.9% of the United States population identified as White alone and not Hispanic or Latino, whereas 13.6% of the population identified as Black or African American alone, 19.1% identified as Hispanic or Latino, 6.3% identified as Asian alone, 1.3% identified as American Indian or Alaska Native alone, and 3% identified as two or more races.³⁴ The American Association of Medical College’s 2022 data reveal that only 3.8% of United States medical school faculty identify as Black or African American (alone), and 3.5% identify as Hispanic, Latino, or of Spanish origin (alone).³⁵ Those numbers inch up to 4.1% and 6%, respectively, when in combination with another race or ethnicity.³⁶ Less than 1% identified as American Indian or Alaska Native or as Native

30. *Id.*

31. *Id.* at 25–30.

32. JESSICA BENNETT ET AL., STRENGTHENING PATHWAYS TO FACULTY CAREERS IN STEM: RECOMMENDATIONS FOR SYSTEMIC CHANGE TO SUPPORT UNDERREPRESENTED GROUPS, ASSOCIATION OF PUBLIC & LAND-GRANT UNIVERSITIES 1, 6 (2020), www.aplu.org/wp-content/uploads/strengthening-pathways-to-faculty-careers-in-stem-recommendations-for-systemic-change-to-support-underrepresented-groups.pdf. The National Science Foundation (“NSF”) considers Hispanics, Black people, American Indians or Alaska Natives, Native Hawaiians, or Other Pacific Islanders as underrepresented minorities. NAT’L SCI. FOUND., DIVERSITY AND STEM: WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES (2023), <https://nces.nsf.gov/pubs/nsf23315/report#>. But, as recently as 2017, NSF included Asians in the list of underrepresented minorities. NAT’L SCI. FOUND., WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN SCIENCE AND ENGINEERING (2017), <https://www.nsf.gov/statistics/2017/nsf17310/digest/introduction/>. This previous underrepresentation has continuing effects within the scientific community.

33. *Quick Facts*, U.S. CENSUS BUREAU, <https://www.census.gov/quickfacts/fact/table/US/POP010220> (last visited Dec. 15, 2023).

34. *Id.*

35. *U.S. Medical School Faculty by Race/Ethnicity (Alone and in Combination)*, AM. ASS’N OF MED. COLLS. (Dec. 31, 2022), <https://www.aamc.org/media/41566/download>.

36. *Id.*

Hawaiian or Other Pacific Islander.³⁷ In contrast, 21.2% of medical school faculty identified as Asian (alone).³⁸

The underrepresentation also extends to success in receiving grant funding, an essential element for STEM faculty.³⁹ A 2011 publication evaluated the association between NIH applicants' self-identified race or ethnicity and the probability of receiving an award.⁴⁰ The paper concluded that "[a]fter controlling for the applicant's educational background, country of origin, training, previous research awards, publication record, and employer characteristics, . . . [B]lack or African-American applicants remain 10 percentage points less likely than [W]hites to be awarded NIH research funding."⁴¹ The gap was less between Asian and Hispanic applicants and White applicants, but still present.⁴² While recent NIH data suggest that the funding gap narrowed since the 2011 study, the gaps remain.⁴³ In addition, while the number of self-designated Black and Hispanic applicants increased since 2010, they remain a small percentage of overall applications.⁴⁴

Research in a variety of settings suggests that diverse teams lead to better decision making.⁴⁵ As discussed in Section C, different perspectives can impact the selection of research topics, research design, and interactions with research participants, among other things.⁴⁶ Thus, increasing representation of URM as researchers could lead to research that better reflects all populations and, thus, result in more equitable distribution of its benefits.

37. *Id.*

38. *Id.*

39. Donna K. Ginther et al., *Race, Ethnicity, and NIH Research Awards*, 333 *SCIENCE* 1015, 1015 (2011).

40. *Id.*

41. *Id.* Native Americans were left off the analysis because of their small number. *Id.*

42. *Id.* at 1021.

43. *Racial Disparities in NIH Funding*, NAT'L INSTS. OF HEALTH (June 3, 2023), <https://diversity.nih.gov/building-evidence/racial-disparities-nih-funding> [<https://web.archive.org/web/20230603002936/https://diversity.nih.gov/building-evidence/racial-disparities-nih-funding>] (relying upon figures 5 and 6). These data do not include American Indians or Native Alaskans, Native Hawaiian or Other Pacific Islanders. *Id.*

44. *Compare id.* (figures 3 & 4) *with id.* (figure 2).

45. David Rock & Heidi Grant, *Why Diverse Teams Are Smarter*, *HARV. BUS. REV.* (Nov. 4, 2016), <https://hbr.org/2016/11/why-diverse-teams-are-smarter>; Richard B. Freeman & Wei Huang, *Strength in Diversity*, 514 *NATURE* 305, 305 (2014); Talia H. Swartz et al., *The Science and Value of Diversity: Closing the Gaps in Our Understanding of Inclusion and Diversity*, 220 *J. INFECTIOUS DISEASE* S33, S33–34 (2019).

46. Angela J. Hattery et al., *Diversity, Equity, and Inclusion in Research Teams: The Good, the Bad, and the Ugly*, 12 *RACE & JUST.* 505, 510–15 (2022); Swartz et al., *supra* note 45; *see also infra* Section II.C.

C. *Inequitable Representation in Reviewers of Research*

Unsurprisingly, given the limited number of URM faculty, URMs are also underrepresented among those responsible for critical reviews of research, including the scientific peer reviewers that determine whether funding is received, the IRBs that must approve any research involving human subjects before research can commence, and the journal editors that determine which research is published. NIH data indicate that, in 2022, only 3.7% of peer reviewers identified as Black or African American, 7.1% identified as Hispanic or Latino, 0.3% identified as American Indian or Alaskan, and 0.1% identified as Native Hawaiian or Pacific Islander.⁴⁷ In contrast, 24.4% of peer reviewers identified as Asian.⁴⁸ Moreover, while 8.8% of peer review chairs identified as Hispanic and Latino and 12.1% identified as Asian, it appears that there were *no* chairs in 2017 or 2022 who identified as Black or African American, American Indian or Alaskan, or Native Hawaiian or Pacific Islander.⁴⁹ Similarly, in a recent study of IRBs, only 4.1% of IRB members identified as Black or African American, 5.6% as Hispanic or Latino, 5.3% as Asian, 1.7% as American Indian or Alaska Native, and no respondent identified as Native Hawaiian or Pacific Islander.⁵⁰ For IRB Chairs (or Chair/Administrators), only 1.5% identified as Black or African American, 2.5% as Hispanic or Latino, 4.5% as Asian, 0.4% identified as American Indian or Alaska Native, and no respondent identified as Native Hawaiian or Pacific Islander.⁵¹ Finally, a 2021 study reported that among editors at the twenty-five leading medical and scientific journals, only 1.1% identified as Black or African American, 3.8% identified as Hispanic or Latino, 14.9% identified as Asian, and 0.3% identified as Pacific Islander; no respondents identified as American Indian or Native American.⁵²

47. *CSR Data & Evaluations*, CTR. FOR SCI. REV, NAT'L INSTS. OF HEALTH (Dec. 8, 2023), <https://public.csr.nih.gov/AboutCSR/Evaluations>.

48. *Id.*

49. *Id.*

50. SANDRA H. BERRY ET AL., PROFILE OF INSTITUTIONAL REVIEW BOARD CHARACTERISTICS PRIOR TO THE 2019 IMPLEMENTATION OF THE REVISED COMMON RULE 22 (2019), https://www.rand.org/pubs/research_reports/RR2648.html.

51. *Id.* While this study represents only a sample of IRB members and chairs nationwide, an earlier study found similar underrepresentation, reporting that only 1% of IRB chairs identified as African American, 3% identified as Asian or Pacific Islander, and less than 1% identified as Hispanic. Joseph A. Catania et al., *Survey of U.S. Boards That Review Mental Health-Related Research*, 3 J. EMPIRICAL RSCH. ON HUM. RSCH. ETHICS 71, 75 (2008). They reported (on average) only 14% of members belong to any ethnic or racial minority group and 24% reported no ethnic minority members. *Id.*

52. James W. Salazar et al., *Gender, Race, Ethnicity, and Sexual Orientation of Editors at Leading Medical and Scientific Journals: A Cross-Sectional Survey*, 181 JAMA INTERNAL MED. 1248, 1248 (2021). The study also reported on gender, with 50.8% reporting as male, 48.1% reporting as female, 0.3% reporting as nonbinary, and 0.8% providing no answer. *Id.*

D. Inequitable Access to the Benefits of Research

The inequitable representation of historically minoritized populations as research participants, researchers, and reviewers results in an uneven distribution of the benefits of research. In its 2003 report, *Unequal Treatment*, the Institute of Medicine (“IOM”) concluded, “[e]vidence of racial and ethnic disparities in health[]care is, with few exceptions, remarkably consistent across a range of illnesses and health[]care services . . . [that] remain even after adjustment for socioeconomic difference and other health[]care access related factors,”⁵³ such as insurance.

Unfortunately, two decades after that IOM report, such disparities persist.⁵⁴ A report on a 2010 IOM workshop to evaluate progress in reducing health disparities identified the “[p]ersistence of health disparities” as one of its key themes, noting that these “disparities are not going away.”⁵⁵ It also highlighted the continued impact of institutional racism and racial discrimination, the link between race, ethnicity, and income in the United States, and the corresponding link between poverty and poor health outcomes.⁵⁶ Reports reflecting on the twentieth anniversary of *Unequal Treatment* report comment on the lack of change over the course of two decades.⁵⁷ These conclusions are supported by research across a variety of diseases and conditions.⁵⁸ For example, a recent review of cancer disparities concluded that

53. INST. OF MED., *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTHCARE* 5 (Brian D. Smedley et al. eds., 2003).

54. INST. OF MED., *HOW FAR HAVE WE COME IN REDUCING HEALTH DISPARITIES?: PROGRESS SINCE 2000* 4 (2012).

55. *Id.*

56. *Id.*

57. See, e.g., Usha Lee McFarling, *20 Years Ago, a Landmark Report Spotlighted Systemic Racism in Medicine. Why Has So Little Changed?*, STAT (Feb. 23, 2022), <https://www.statnews.com/2022/02/23/landmark-report-systemic-racism-medicine-so-little-has-changed/> (“But today, the disparities—poorer outcomes and higher death rates for nearly every medical condition the panel examined—and the structural racism underlying them, remain. That grim truth has been made startlingly clear by both the pandemic and by statistics that show Black Americans continue to die up to five years earlier than those who are white.”); Michael Blanding, *Revisiting the ‘Unequal Treatment’ Report, 20 Years Later*, HARV. PUB. HEALTH (Oct. 3, 2022), <https://harvardpublichealth.org/alumni-post/revisiting-the-unequal-treatment-report-20-years-later/> (“In the intervening two decades, the gap between [W]hite people and racial and ethnic minorities has remained frustratingly persistent, with little concrete progress to show for the efforts that have been made to close it.”).

58. A PubMed search for “health disparities” limited to the last 5 years and to reviews or systematic reviews returns 5,759 results. The following disease specific examples show the variety. See, e.g., Lilyana Amezcua, *Health Disparities, Inequities, and Social Determinants of Health in Multiple Sclerosis and Related Disorders in the US: A Review*, 78 JAMA NEUROLOGY 1515 (2021); Ani Kardashian et al., *Health Disparities in Chronic Liver Disease*, 77 HEPATOLOGY 1382 (2023); Ankita Devareddy et al., *Health Disparities Across the Continuum of ASCVD Risk*, 24 CURRENT CARDIOLOGY REPS. 1129 (2022); Lesli E. Skolarus, *Considerations in Addressing Social Determinants of Health to Reduce Racial/Ethnic Disparities in Stroke Outcomes in the United States*, 51 STROKE 3433 (2020); Emily Brigham et al., *Health Disparities in Environmental and Occupational Lung Disease*, 41 CLINICS CHEST MED. 623 (2020).

[d]espite great progress in our understanding of factors that contribute to racial/ethnic disparities in cancer incident, tumor biology and outcomes, disparities still exist, and multidisciplinary efforts are needed to ameliorate or eliminate them.⁵⁹

A 2019 study on treatment in end-stage renal disease (“ESRD”) concluded “that racial differences in PCI [percutaneous coronary intervention] in the ESRD population have persisted since Daumit et al. first reported their results of an analysis of 4987 ESRD patients initiated on dialysis in 1986–1987.”⁶⁰ In addition, a 2023 study of Medicare beneficiaries with disability and active opioid use disorder (“OUD”) symptoms “observed substantial racial and ethnic disparities in the receipt of medications for OUD, particularly among Black beneficiaries. The disparities were not explained by state of residence or observable differences in beneficiary age, sex, or burden of chronic conditions across groups.”⁶¹

These differences are also not explained by access to health care, as beneficiaries had the same coverage and engaged in similar interactions with primary care providers.⁶² The disparities extend to the tools used by health care professionals to assess, diagnose, and treat patients.⁶³ For example, pulse oximeters fail to identify clinically low oxygen levels among Black patients.⁶⁴ The authors noted the significance of their finding, stating that “[g]iven the widespread use of pulse oximetry for medical decision making, these findings have some major implications, especially during the current coronavirus disease 2019 (COVID-19) pandemic.”⁶⁵

Pulse oximeters may provide less accurate results for women and children, as well.⁶⁶ Bias is also identified in clinical algorithms. For example, lung function equations use a correction factor based on faulty assumptions about Black patients that have recently been shown to have negative clinical implications.⁶⁷ Similarly, two leading nephrology societies recently recommended removal of

59. Valentina A. Zavala et al., *Cancer Health Disparities in Racial/Ethnic Minorities in the United States*, 124 *BRIT. J. CANCER* 315, 324 (2021).

60. Robert Nee et al., *Use of Percutaneous Coronary Intervention Among Black and White Patients with End-Stage Renal Disease in the United States*, 8 *J. AM. HEART ASS'N* 1, 6 (2019).

61. Michael L. Barnett et al., *Racial Inequality in Receipt of Medications for Opioid Use Disorder*, 388 *NEW ENG. J. MED.* 1779, 1786 (2023).

62. *Id.*

63. See generally Achuta Kadambi, *Achieving Fairness in Medical Devices*, 372 *SCI.* 30 (2021).

64. Michael W. Sjöding et al., *Racial Bias in Pulse Oximetry Measurement*, 383 *NEW ENG. J. MED.* 2477, 2478 (2020).

65. *Id.*

66. Michael W. Sjöding et al., *Origins of Racial and Ethnic Bias in Pulmonary Technologies*, 74 *ANN. REV. MED.* 401, 407 (2023).

67. *Id.*

race from kidney function estimating equations.⁶⁸ A recent KFF Health News story described how typical electroencephalogram (“EEG”) instructions and approaches fail to account for differences in hair texture and style preferences that could discourage or even prevent Black people from receiving necessary care, with potential financial consequences, as well.⁶⁹

Important health and public health questions remain unfunded, unaddressed, and sometimes even unasked. For example, the clinical definition of AIDS failed to address symptoms unique to women and HIV research often excluded women, despite the number of women with the disease.⁷⁰ Even the NIH initially “rejected women centered grants in HIV” on grounds “it was unnecessary to understand co-factors of HIV in low income ethnic minority women.”⁷¹

Similarly, a recent study documented the disparities in federal and private funding of research on sickle cell disease (“SCD”) and cystic fibrosis (“CF”).⁷² Both diseases are “inherited disorders associated with intermittent disease exacerbations that require hospitalizations and with a substantial reduction in the median life span.”⁷³ SCD primarily affects Black people, whereas CF affects primarily White people; SCD is more common, affecting 1 in 365 Black Americans; CF affects 1 in 2500 White Americans.⁷⁴ “Despite SCD being 3 times as prevalent as CF, both diseases received a similar amount of federal government research funding between 2008 and 2018,” further noting “[t]he funding disparity was markedly increased when factoring in disease-specific private foundation funding.”⁷⁵ The authors note the roughly equivalent (federal) or greater (foundation) funding of research for CF seems to deviate from the general principle of funding based on disease burden.⁷⁶ Moreover, this difference

68. Abinet Aklilu & Cynthia Delgado, *The Removal of Race from Kidney Function Estimation: Key Points for Primary Providers*, 114 J. NAT'L MED. ASS'N S25, S27 (2022).

69. Tarena Lofton, *How One Patient's Textured Hair Nearly Kept Her from a Needed EEG*, KFF HEALTH NEWS (Apr. 27, 2023), <https://kffhealthnews.org/news/article/black-textured-hair-eeeg-racial-barriers>.

70. Ramani Durvasula, *A History of HIV/AIDS in Women: Shifting Narrative and a Structural Call to Arms*, AM. PSYCH. ASS'N: PSYCH. & AIDS EXCH. NEWSL., Mar. 2018, <https://www.apa.org/pi/aids/resources/exchange/2018/03/history-women> [<https://web.archive.org/web/20210625092613/https://www.apa.org/pi/aids/resources/exchange/2018/03/history-women>]; Philip J. Hiltz, *AIDS Definition Excludes Women, Congress Is Told*, N.Y. TIMES, Jun. 7, 1991, at A19.

71. Durvasula, *supra* note 70 (citing GENA COREA, *THE STORY OF WOMEN WITH AIDS: THE INVISIBLE EPIDEMIC* (1992)).

72. Faheem Farooq et al., *Comparison of US Federal and Foundation Funding of Research for Sickle Cell Disease and Cystic Fibrosis and Factors Associated with Research Productivity*, 3 JAMA NETWORK OPEN 1 (2020).

73. *Id.* at 1.

74. *Id.*

75. *Id.* at 3.

76. *Id.*

resulted in a real life impact, as “[t]he additional research support was associated with greater research productivity and pharmaceutical development for CF compared with SCD.”⁷⁷

As the foregoing demonstrates, underrepresentation of historically minoritized populations is pervasive and persistent across all components of the research enterprise. Before turning to recommendations for addressing this problem and implementing justice in research,⁷⁸ it is first necessary to understand how justice has been and should be conceptualized in the research context.

III. CONCEPTUALIZING JUSTICE IN RESEARCH ETHICS

A. *Traditional Conception of Justice—The Belmont Report*

After AP reporter Jean Heller⁷⁹ revealed that, for over forty years, the Public Health Service—a United States Government agency—conducted a study of untreated syphilis among 400 poor, Black men from rural Alabama, Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.⁸⁰ Among other things, the Commission drafted the Belmont Report, which established three basic principles governing human subjects research: respect for persons, beneficence, and justice.⁸¹

The Belmont Report presented the central question on justice in research as: “Who ought to receive the benefits of research and its burdens?”⁸² In answering this question, it appeals to the Aristotelian notion of treating like individuals alike, while simultaneously noting the need to determine “who is equal and who is unequal” and when departures from equal distributions are justifiable. In response, the Report describes the multiple “widely accepted formulations of just ways to distribute burdens and benefits,” which include: “(1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to

77. *Id.* at 3–4.

78. *See infra* Part III.

79. *See* Allen G. Breed, *How an AP Reporter Broke the Tuskegee Syphilis Story*, ASSOCIATED PRESS (July 25, 2022 8:00 AM), <https://apnews.com/article/tuskegee-study-experiment-syphilis-7743bd8c7d51fe0ef9a855b4bec69b1f> (describing Jean Heller’s reporting on Tuskegee Study).

80. BELMONT REPORT, *supra* note 1. The researchers did not inform the men they had syphilis, and, over the course of the study, the researchers actively prevented the men from receiving effective treatment. Accordingly, the men unwittingly risked transmitting the disease to their partners who, for some, could then transmit to children during pregnancy. A.M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8 HASTINGS CTR. REP. 21, 24, 25–26 (1978); FRED D. GRAY, *THE TUSKEGEE SYPHILIS STUDY* 80–99 (1998). As Patricia King wrote, the selection of these research subjects is no accident—and reflects the injustice inherent in the study. King, *supra* note 2, at 113–15; Brandt, *supra* note 80, at 23–26.

81. BELMONT REPORT, *supra* note 1, at 4.

82. *Id.* at 8.

societal contribution, and (5) to each person according to merit.”⁸³ We appeal to these different formulations, depending on the circumstances. For example, in the COVID-19 vaccine context, there are appeals both to distributing based on need in prioritizing the elderly and people with underlying health conditions and to distribution based on social contributions in prioritizing health care workers and other essential workers.⁸⁴ But, as this example suggests, there may be different ways to achieve a just distribution—and reasonable minds may differ about how and when we achieve it. Moreover, the answers to each of the questions the Belmont Report poses will vary depending on who gets to decide. Injustices occur and persist when diverse voices are excluded from decision making.

The Belmont Report’s discussion of justice is explicitly set against the backdrop of the Tuskegee Syphilis Study, as well as other historic research abuses of marginalized populations.⁸⁵ It describes the Tuskegee Syphilis Study as “us[ing] disadvantaged, rural [B]lack men to study the untreated course of a disease that is by no means confined to that population” and “depriv[ing subjects] of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.”⁸⁶ It is therefore not surprising that the Report takes a primarily protective stance in conceptualizing justice, urging researchers, as a matter of justice, to ensure the benefits of research—or least publicly funded research—go to all, while also scrutinizing “the selection of research subjects . . . in order to determine whether some classes . . . are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.”⁸⁷

In application, justice is about equitable selection of subjects, with a focus on avoiding exploitation. The federal regulations governing human subjects research (referred to as the Common Rule) reflects this concept of justice in its criteria for IRB approval. This provision further provides that

[i]n making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are

83. *Id.* at 9.

84. See, e.g., Kathleen Dooling et al., *The Advisory Committee on Immunization Practices’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine – United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1857 (2020). For a deeper discussion of these principles, see KATHY KINLAW & ROBERT LEVINE, CTRS. FOR DISEASE CONTROL & PREVENTION, ETHICAL GUIDELINES IN PANDEMIC INFLUENZA (2007), https://www.cdc.gov/os/integrity/phethics/docs/panFlu_Ethic_Guidelines.pdf.

85. BELMONT REPORT, *supra* note 1, at 9.

86. *Id.*

87. *Id.* at 9–10.

vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.⁸⁸

But the regulations do not provide specific guidance on how to apply this criterion.⁸⁹

B. A Broader Conception of Justice: Research as A Benefit

The AIDS epidemic challenged this protective approach to justice in research: those who had AIDS—then, an almost universally fatal condition with no proven effective treatment—wanted in. AIDS patients wanted the opportunity to participate in research and the possibility, however remote, that the research could alter their disease course—or at least provide information that could benefit others. AIDS activists also demanded greater input into the kind of research conducted, resulting in the creation of community advisory boards.⁹⁰ Similarly, breast cancer activists soon after joined in the calls for more inclusion in research as a matter of justice.⁹¹

This changing perception of research as a benefit to which people want access, rather than something from which participants need protection,⁹² ultimately led to government policies requiring the inclusion of women and minorities in research. In 1993, Congress amended the Public Health Service Act to require “inclusion of women and minorities in clinical research,” unless such inclusion is “inappropriate with respect to the health of the subjects,” “the purpose of the research,” or “under such other circumstances that the Director of NIH may designate.”⁹³ NIH policy requires a “clear and compelling rationale and justification” to exclude these populations from clinical research.⁹⁴ In addition,

88. 45 C.F.R. § 46.111(a)(3) (2023).

89. In contrast, the regulations follow the Belmont Report’s requirement for informed consent, but also outline specific types of information that are required in the consent process, unless specified waiver criteria are met. 45 C.F.R. §§ 46.111(a)(4), 46.116 (2023).

90. Stephen F. Morin et al., *Community Consultation in HIV Prevention Research: A Study of Community Advisory Boards at 6 Research Sites*, 33 J. AIDS 513, 514 (2003).

91. See generally Janet R. Osuch, *A Historical Perspective on Breast Cancer Activism in the United States: From Education and Support to Partnership in Scientific Research*, 21 J. WOMEN’S HEALTH 355 (2012).

92. 1 WOMEN AND HEALTH RESEARCH: ETHICAL AND LEGAL ISSUES OF INCLUDING WOMEN IN CLINICAL STUDIES 77 (Anna C. Mastroianni et al. eds., 1994) (“[A]ttention has turned away from the problem of unduly subjecting certain groups to disproportionate risks and toward the problem of denying the benefits of research to certain classes of people who have not frequently been the subjects of research.”).

93. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 101, 107 Stat. 122, 133–35 (1993) (codified at 42 U.S.C. § 289a-2).

94. *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*, NAT’L INSTS. OF HEALTH (Dec. 6, 2017), <https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm>.

FDA withdrew its policy restricting inclusion of women of childbearing potential.⁹⁵

Despite this changing perspective and adoption of policies to promote more inclusive research, as described in Part II,⁹⁶ inequities remain, and more action is needed. There is no doubt that many of these failures reflect broader injustices embedded in our society. The Belmont Report recognized the limit of its justice principle in the face of systemic injustices, stating:

injustice arises from social, racial, sexual, and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if institutional review boards are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research.⁹⁷

But that does not absolve the research community from the obligation to take positive steps to challenge these injustices and advance justice within research. The next step is to assess specific actions that are necessary more fully to implement justice in research.

IV. IMPLEMENTING JUSTICE IN RESEARCH

It is imperative to take advantage of the recent focus on justice to reorient how to approach oversight in research involving human subjects to achieve more inclusive research. In considering how to implement justice in research, there are limits, of course, to what individuals and certain stakeholders can achieve within their respective roles, at least as currently constituted. Long lasting change requires coordinated effort among all stakeholders. But there is still much we can do within existing structures to start creating important change in the short term, and these efforts will cement our commitments to justice in research in the generations that follow.

A. *Conducting Inclusive Reviews*

1. *IRBs*

IRBs play a critical role in the research community. Human subjects research that is conducted or funded by the federal government generally requires IRB approval before research can commence.⁹⁸ In addition, research that

95. Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. 39406, 39408 (Jul. 22, 1993).

96. *See supra* Part II.

97. BELMONT REPORT, *supra* note 1, at 9.

98. *See generally* 45 C.F.R. § 46.101–24 (also known as the “Common Rule”). Promulgated by the Department of Health and Human Services, nineteen other agencies agreed to follow the Common Rule requirements, but the mechanism by which they accomplish compliance varies. *Federal Policy for the*

supports approval of FDA regulated products also must receive approval by an IRB before commencing.⁹⁹ Thus, their role in implementing justice is an appropriate place to start. IRBs can and should encourage more inclusive research through the questions they pose to researchers, the changes they suggest or require, and the education they provide to researchers.

The regulations require IRBs to determine that “selection of subjects is equitable.”¹⁰⁰ In making this assessment, the IRB should consider the purposes of the research and the setting in which the research will be conducted.”¹⁰¹ And yet, a researcher who specifies that “participants of any gender, race, or ethnicity are eligible for this study” arguably satisfies this requirement. As a formal matter, there is no intention to exclude individuals based on these characteristics. But study design choices could undermine that stated intention. Choices about where to recruit and where to perform the research, whether to compensate participants, whether to translate documents or employ multilingual research staff, and exclusions based on certain comorbidities can all influence who ultimately participates in a study.¹⁰² These choices also influence who may receive benefits from the research. It is the IRB’s responsibility to probe into those design choices to ensure they are justified and that the selection of subjects is, in fact, equitable.

What are some of the ways that study design choices can undermine inclusive research? Unexamined exclusion criteria are one area that can impact the representativeness of a study sample.¹⁰³ Although FDA policies no longer support the exclusion of women of childbearing potential in pharmaceutical studies, many studies continue to exclude women of childbearing potential, reflecting previous studies.¹⁰⁴ If IRBs simply accept that decision without asking

Protection of Human Subjects (‘Common Rule’), OFFICE FOR HUM. RSCH. PROTS. (OHRP), U.S. DEP’T HEALTH & HUM. SERVS. (Dec. 13, 2022), <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>. Although the Common Rule has been amended since this paper was published, the basic structure remains the same.

99. 21 C.F.R. § 56.103(a) (2023). The Common Rule and FDA human subjects regulations are “made as compatible as possible under their respective statutory authorities.” OHRP, *supra* note 98.

100. 45 C.F.R. § 46.111(a)(3) (2023).

101. *Id.*

102. Stuart S. Winter et al., *Inclusion of Special Populations in Clinical Research: Important Considerations and Guidelines*, 4 J. CLINICAL & TRANSLATIONAL RSCH. 56, 61 (2018); Jean G. Ford et al., *Barriers to Recruiting Underrepresented Populations to Cancer Clinical Trials: A Systematic Review*, 122 CANCER 228, 231, 236 (2008).

103. Indorewalla et al., *supra* note 26, at 929.

104. See *Gender Studies*, *supra* note 20 (discussing historical exclusion of women from clinical trials). Recent research documents that exclusions persist, despite policy changes. See, e.g., Daitch et al., *supra* note 22; Kelly M. Kons et al., *Exclusion of Reproductive-Aged Women in COVID-19 Vaccination and Clinical Trials*, 32 WOMEN’S HEALTH ISSUES 552, 558 (2022); Alannah L. Phelan et al., *Exclusion of Women of Childbearing Potential in Clinical Trials of Type 2 Diabetes Medications: A Review of Protocol-Based Barriers to Enrollment*, 39 DIABETES CARE 1004, 1005–07 (2016). See THE PHASES WORKING GROUP, *ENDING THE EVIDENCE GAP FOR PREGNANT WOMEN AROUND HIV & CO-INFECTIONS* 22–24 (2020), for a discussion of the scientific and ethical rationale for research involving pregnant women.

researchers for justification, then studies may unnecessarily exclude women from research and thus, leave women unable to reap the benefits. IRBs should ask whether there are alternatives to exclusion, such as requiring effective contraception. If the use of contraception cannot mitigate the risk, IRBs should inquire whether sexually active men capable of impregnating a woman should also be excluded, so that the burden of exclusion is not born solely by women.

Similarly, studies often exclude people with certain diagnoses (e.g., diabetes) or with certain lab results (e.g., glucose levels).¹⁰⁵ Some of these exclusions are necessary to protect the safety and well-being of participants.¹⁰⁶ But it is also possible that exclusion criteria adopted for earlier phases are no longer needed at later phases of the trial. It is also possible that they have been copied from other protocols¹⁰⁷ and may no longer be needed (e.g., if sufficient safety data has been collected) or they may not be applicable to the new study. Given the disparate impact exclusion criteria can have on who is eligible for the study, it is essential that IRBs inquire about the justification for exclusion criteria if the researcher fails to provide justification in the submitted protocol.¹⁰⁸ For example, research suggests that common exclusion criteria for Alzheimer's Disease research, including hypertension, cardiovascular disease, stroke history, depression, and substance use, "would exclude approximately 94.8% of participants listed in an [AD] clinical registry."¹⁰⁹ It is difficult to see how those who remain eligible are representative of the population.¹¹⁰ The lack of representativeness is exacerbated given the disproportionate impact of cardiovascular disease among African Americans.¹¹¹ Returning to the diabetes example, data from the National Diabetes Statistics Report concludes that "prevalence of diagnosed diabetes was highest among American Indians/Alaska Natives (14.7%), people of Hispanic origin (12.5%), and non-Hispanic [B]lacks (11.7%)," although the "prevalence of prediabetes was similar among all

105. See generally Jinzhang He et al., *Exclusion Rates in Randomized Controlled Trials of Treatments for Physical Conditions: A Systematic Review*, 21 TRIALS 228 (2020).

106. Indorewalla et al., *supra* note 26, at 929.

107. *Id.* (citations omitted) ("Too often clinical researchers rely on longstanding and arbitrary exclusion criteria 'carried over' from previous, similar studies . . . For example, past research has found that cognitive impairment is frequently used as an exclusion criteria in geriatric research; however, a majority of such researcher offered no rationale in support of using such exclusion criteria.")

108. Various studies demonstrate that exclusion criteria are often poorly supported. See Indorewalla et al., *supra* note 26, at 929 (noting that unsupported decisions to exclude participants based on cognitive impairment "systematically exclude the very participants who are intended to benefit from novel interventions resulting from [Alzheimer's Disease] clinical trials."); see also Andrea L. Gilmore-Bykovskiy et al., *Recruitment and Retention of Underrepresented Populations in Alzheimer's Disease Research: A Systematic Review*, 5 ALZHEIMER'S & DEMENTIA: TRANSLATIONAL RSCH. & CLINICAL INTERVENTIONS 751, 767 (2019) (commenting on exclusion of certain populations).

109. Indorewalla et al., *supra* note 26, at 929.

110. *Id.*

111. *Id.*

racial/ethnic groups.”¹¹² Given that an exclusion criterion of diagnosed diabetes would disproportionately exclude people of color, IRBs should ask for justification. If there is a legitimate safety concern, IRBs should inquire whether there are alternative methods of protection. For example, is there some form of monitoring that would provide adequate protection while avoiding the disproportionate exclusion of people of color?¹¹³

Undoubtedly, IRBs can expect some push back if they begin asking these questions. Whether IRBs ought to evaluate science is a common subject of debate, with some suggesting that this function falls outside the IRBs’ purview, particularly when scientific review already occurred.¹¹⁴ But, as these examples should demonstrate, the underlying science is inextricably tied to the ethics of the research.¹¹⁵ IRBs are tasked with assessing the risks and benefits of the study and the subject selection, along with the consent processes.¹¹⁶ A 2000 article identified seven ethical requirements for clinical research.¹¹⁷ Five of these concerned IRBs’ essential function (independent review) or the principles and the criteria reflected in the regulations (fair subject selection, favorable risk-benefit ratio, informed consent, and respect for potential and enrolled subjects).¹¹⁸ The remaining requirements relate to the underlying science. One requirement is that the research must have value—that is, it will generate information that can lead to improvements in health or well-being either directly or by providing the underlying science that can do so.¹¹⁹ The other requirement is that the research must have scientific validity—that is, it is conducted in a way that meets scientific standards for rigor and will lead to reliable information.¹²⁰ In short, if the underlying science is not justified, then it is not ethical to involve human subjects. As the entity tasked with implementing the regulations to protect

112. CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH & HUM. SERVS., NATIONAL DIABETES STATISTICS REPORT 2020: ESTIMATES OF DIABETES AND ITS BURDEN IN THE UNITED STATES 4, 8 (2020).

113. See, e.g., *Diabetes and African Americans*, OFF. OF MINORITY HEALTH, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://minorityhealth.hhs.gov/diabetes-and-african-americans> (last visited Dec. 15, 2023).

114. See, e.g., Charles W. Lidz & Suzanne Garverich, *What the ANPRM Missed: Additional Needs for IRB Reform*, 41 J.L. MED & ETHICS 390, 394–95 (2013) (recommending “outsourcing” of scientific issues from IRB review stating that authors “also believe that IRBs are an inappropriate mechanism to review the scientific design or methods of studies” and noting favorably institutions that established a scientific review process within departments before IRB submission).

115. *Id.* (stating authors “are not suggesting . . . that the quality of science is irrelevant to the ethics of research” while arguing for a separate scientific review process).

116. 21 C.F.R. § 50.24, 50.27.

117. See generally Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?*, 283 JAMA 2701, 2701 (2000).

118. *Id.* at 2704–07.

119. *Id.* at 2703.

120. *Id.* at 2704.

the rights and well-being of human subjects, IRBs are obligated to ask these questions.

Of course, exclusion criteria are not the only part of study design that can undermine equitable selection. Decisions about how and where to recruit, where and how often study procedures take place, and whether, how, and how much participants are paid can all influence the makeup of the resulting study population.¹²¹ If recruiting takes place within a university (e.g., posted within the psychology building), the study population will be different than if recruiting takes place in a community setting (e.g., posted within a coffee shop, church, barbershop, etc.). The same is true if it takes place within an academic medical center instead of a safety net hospital; these settings serve different people. IRBs should consider those differences and ask researchers about the impact of their recruitment strategies on equitable selection of subjects.¹²² Similarly, if study procedures take place at locations far away from diverse communities, inaccessible by public transportation, or only open during business hours, inclusiveness may suffer.¹²³ Alzheimer's Disease research often requires enrollment of a study partner, because participants' cognitive impairment may interfere with their ability to provide the necessary data.¹²⁴ But, because many older adults do not have spouses, recruitment will be impacted if researchers rely too heavily on spouses or if they fail to account for the needs of non-spousal study partners, such as an adult children.¹²⁵

Failure to reimburse participants for their out of pocket expenses, such as travel costs, parking, or childcare, or to compensate them adequately for their time, especially if they must miss work to participate, may similarly skew the study population.¹²⁶ IRBs should ask questions about how these choices may impact the ability of some populations to participate and encourage researchers to consider their options to accommodate a more diverse group of participants. As discussed below, data from qualitative studies among diverse populations indicate a need to alter our approaches to participant compensation.¹²⁷ Although providing payments that can be used broadly rather than being tied to a single

121. Winter et al., *supra* note 102; Jennifer Cunningham-Erves et al., *A Community-Informed Recruitment Plan Template to Increase Recruitment of Racial and Ethnic Groups Historically Excluded and Underrepresented in Clinical Research*, 125 CONTEMP. CLINICAL TRIALS 1, 3, 5–7 (2023).

122. David H. Strauss et al., *Justice, Diversity, and Research Ethics Review*, 371 SCI. 1209, 1210 (2021).

123. Cunningham-Erves et al., *supra* note 121, at 2.

124. Indorewalla et al., *supra* note 26, at 930.

125. *Id.*

126. *Addressing Ethical Concerns Regarding Offers of Payment to Research Participants*, SEC'Y'S ADVISORY COMM. ON HUM. RSCH. PROTS., OHRP (Oct. 18, 2019), <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-september-30-2019/index.html>; Luke Gelinas et al., *A Framework for Ethical Payment to Research Participants*, 378 NEW ENG. J. MED. 766, 768–69 (2018); Winter et al., *supra* note 102, at 59–60, 64.

127. *See infra* Section IV.B.1.

store increases research costs (as these gift cards have a fee associated with them), it is necessary to provide the flexibility to research participants.¹²⁸ Further, institutional policies may introduce additional and unnecessary barriers. For example, institutional requirements to collect identifying information, including Social Security numbers, may deter some populations from participating.¹²⁹ Both researchers and IRBs should engage the communities in which they work to understand how their policies may interfere with the goal of inclusive research.

What the Article suggests here requires IRBs to ask more probing questions about study design than completed in the past, but such questions are necessary to meet their obligations regarding the assessment of equitable selection and implementing justice in research.¹³⁰ A recent paper provides a list of points to consider that is an excellent place for IRBs to start.¹³¹ The authors recommend questions for initial review that focus on: (1) the match between the study aims and the demographics of the proposed sample; (2) the effects of the inclusion and exclusion criteria on the study populations and alternatives to exclusion to minimizing risk; (3) recruitment strategies; (4) study conduct in ways that meet the needs of the underrepresented groups; (5) sufficient payment; and (6) return of results to meet the needs of populations.¹³² The last point responds to concerns about exploitation. Importantly, the authors remind IRBs to assess equitable selection in continuing review and inquire whether the recruited population is representative and adequate to address study goals.¹³³

As the authors note, “simply asking the question[s] will prompt consideration by investigators.”¹³⁴ As researchers come to realize that these questions are an integral part of the IRB review and approval process, they will begin to incorporate them earlier into their design process. While IRBs can play a critical role in implementing justice in research, they should not have to do it alone.

128. Spencer Tierney, *Gift Card vs. Prepaid Debt Card: What's the Better Gift?*, NERDWALLET (Dec. 7, 2023), <https://www.nerdwallet.com/article/banking/gift-card-vs-prepaid-debit-card-whats-the-better-gift>.

129. Cathy Samayoa et al., *Participant-Centered Strategies for Overcoming Barriers to Biospecimen Collection among Spanish-Speaking Latina Breast Cancer Survivors*, 29 *CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION* 606, 610 (2020); James M. DuBois, *Crossing a Boundary?*, 46 *MONITOR ON PSYCH.* 70, 70 (2015).

130. Winter et al., *supra* note 102, at 57, 62, 65 (suggesting questions for researchers to achieve similar goals).

131. Strauss et al., *supra* note 122, at 1210.

132. *Id.*

133. *Id.* The specific questions are as follows: Has the study fulfilled its recruitment and accrual goals?; Is demographic distribution on track to approximate the study goals; and, If not, are adequate corrective actions described, sufficient, and likely to be successful? *Id.*

134. *Id.*

2. Funders

Funders could accelerate IRBs' efforts to implement justice in research by incorporating the types of questions described above into their scientific review processes. Doing so would provide a signal of the importance of careful considerations of study design choices that implicate justice early in the research development process. It would also provide a powerful incentive to comply.

There is precedent for doing so. In the late 1990s/early 2000s, the NIH placed greater weight on the human subjects protections section of the grant than in previous years. Not only did NIH place greater scrutiny on investigators' attention to the questions in that section, but studies that received fundable scientific scores did not receive funding, due to questions about the human subjects protections.¹³⁵

At the time, I was a member of the University of California San Francisco ("UCSF") Centers for AIDS Prevention Studies ("CAPS") Policy & Ethics Core. My prevention science colleagues conducted cutting edge research that prompted human subjects concerns. Although attentive to these concerns, my colleagues needed advice on how to express the ethical justifications for their design choices in the detail NIH now required to obtain the funding their scientific questions merited. Before the policy change, these researchers would not have faced those considerations until they sought IRB approval for their study. I would contend that thinking through the human subjects ethical and regulatory questions at the earliest design stages strengthened the scientific proposals. This experience suggests that researchers would prioritize justice questions in their study designs if funders incorporated these questions into their scientific review process.

Although the Common Rule's review criteria apply to IRB review, its requirements provide justification for funders—at least federal funders—to

135. On May 1, 2000, NIH issued its Revised Policy for IRB Review of Human Subjects Protocols in Grant Applications, which dispensed with the requirement of IRB review before grant submission, given that many grant applications are not funded. Any award is contingent on IRB review. *Id.* at 3; NAT'L INSTS. OF HEALTH, NOT- OD-00-031, REVISED POLICY FOR IRB REVIEW OF HUMAN SUBJECTS PROTOCOLS IN GRANT APPLICATIONS (2000). In 2002, NIH issued reviewer instructions focused on human subjects protections in grant applications. NAT'L INST. OF HEALTH, NIH/OER/OEP V7, NIH INSTRUCTIONS FOR REVIEWERS FOR EVALUATING RESEARCH INVOLVING HUMAN SUBJECTS IN GRANT AND COOPERATIVE AGREEMENT APPLICATIONS 3 (2002). Reviewers are instructed to include a heading "Protection of Human Subjects from Research Risk" in their critiques, with the options of Absent, Acceptable, Unacceptable, or Exempt (from the regulations). Human subjects considerations are explicitly incorporated into scoring of grant applications under this policy. *Id.* at 3 (emphasis omitted) ("If the Protection Of Human Subjects from Research Risk is Unacceptable it should be reflected in the priority score for scientific and technical merit assigned to the application. The negative impact on the score should reflect the seriousness of the human subjects concerns that are identified If the research risks are sufficiently serious and protections against the risks are so inadequate as to consider the proposed research unacceptable on ethical grounds, reviewers may recommend that no further consideration be given to the application and score the application as NRFC (Not Recommended for Further Consideration)"). This revised policy provided similar instructions for inclusion of women and minorities, as well as for data safety monitoring. *Id.* at 5, 13.

consider these criteria as well.¹³⁶ The Department of Health and Human Services (“DHHS”), along with nineteen other federal agencies, apply its provisions to the research they fund.¹³⁷ NIH, the primary funder of biomedical research in the United States, is part of DHHS.¹³⁸ FDA implements its own regulations that largely track the Common Rule.¹³⁹ Accordingly, federal funders are bound by its legal and ethical commitment to the equitable selection of subjects.¹⁴⁰ Even those who are not legally bound by the Common Rule often apply it to the research they fund.¹⁴¹ Moreover, other research ethics codes identify justice as a core principle.¹⁴²

3. Journals

If the research community is serious about implementing justice, it is imperative that it applies consistent standards across all the stages of research such as design, implementation, and dissemination. While IRBs and funders can each impact design and implementation of research, it is up to journals to implement justice in research dissemination. Although publication of research results comes late in the research process, it can still serve as an important lever to encourage researchers to think seriously about the inclusiveness of their studies. Journals already reinforce a variety of scientific and ethical norms, such as requiring specification of authors’ contributions, disclosure of potential financial and nonfinancial conflicts of interests, documentation of IRB review, and depositing of data.¹⁴³ While preventing publication of studies that fail to meet

136. OHRP, *supra* note 98.

137. *Id.*

138. *What We Do: Budget*, NAT’L INSTS. OF HEALTH (Aug. 1, 2023), <https://www.nih.gov/about-nih/what-we-do/budget>.

139. OHRP, *supra* note 98.

140. *Id.*

141. Michelle N. Meyer, *There Oughta Be a Law: When Does(n’t) the U.S. Common Rule Apply?*, 48 J.L. MED. ETHICS 60, 60–62 (2020); Lauren AJ Hartsmith, *Surprise! “Checking the Box” Is Still an Option on the Federalwide Assurance (FWA)*, ADVARRA (Nov. 18, 2020), <https://www.advarra.com/blog/surprise-checking-the-box-is-still-an-option-on-the-federalwide-assurance-fwa/>.

142. BELMONT REPORT, *supra* note 1, at 7, 10.

143. See, e.g., *Roles and Responsibilities of Authors, Contributors, Reviewers, Editors, Publishers, and Owners*, INT’L COMM. OF MED. J. EDS., <https://www.icmje.org/recommendations/browse/roles-and-responsibilities/> (last visited Dec. 16, 2023) (linking to policies on Defining the Role of Authors and Contributors; Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of Interest; Responsibilities in the Submission an Peer-Review Process; Journal Owners and Editorial Freedom; and Protection of Research Participants); *Clinical Trials*, INT’L COMM. OF MED. J. EDS., <https://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html> (last visited Dec. 16, 2023) (describing policies regarding registration of clinical trials and data sharing). There is a long list of journals who agreed to follow these policies, including top ranked science and medicine journals such as *JAMA* and its family of journals, the *New England Journal of Medicine*, the *Lancet*, and the *British Medical Journal* and its family of journals. *Journals Stating That*

justice principles is the strongest option, journals could encourage inclusive research by requiring justification of design choices and specification of limitations resulting from less inclusive designs.¹⁴⁴ Both approaches would undoubtedly help to move the needle.

B. Increasing Representation Across the Research Enterprise

While conducting inclusive IRB, scientific, and journal reviews can go a long way toward improving the implementation of justice, it is not sufficient. Efforts to increase inclusivity and amplify diverse voices in all aspects of research are needed. Directing efforts to community engaged research can alter what research is proposed and how it is conducted. Increasing representation of IRBs can provide more inclusive reviews, while also building community trust in the process. However, sustained progress requires increasing representation among researchers, funders, and institutional leaders.

1. Community-engaged Research

Some commentators suggest that “[t]he IRB should require a statement in the study proposal summarizing the nature, process, input, and impact of such patient and community engagement and how this information has shaped the study itself and the recruitment plan[.]”¹⁴⁵ This suggestion rightly focuses attention on how community engagement can alter the questions researchers ask, how they ask them, and, ultimately, how effective their research is in addressing the questions that matter to the communities in which the work is done.¹⁴⁶

Let me provide some concrete examples. Over my career, I reviewed numerous HIV protocols that ask detailed questions regarding people’s sexual and substance using behaviors. Many used colloquial, explicit language that occasionally offended reviewers. But I am persuaded that it is essential to use the language that the individuals in these communities use to get valid data.¹⁴⁷ Participant understanding of the questions asked is critical to the research question.¹⁴⁸ Similarly, I have heard arguments to make any payments in studies

They Follow the ICMJE Recommendations, INT’L COMM. OF MED. J. EDS., <https://www.icmje.org/journals-following-the-icmje-recommendations/> (last visited Dec. 16, 2023).

144. See *supra* Part III.

145. Strauss et al., *supra* note 122, at 1210.

146. Winter et al., *supra* note 102, at 62–63.

147. For a discussion of these and other challenges in designing effective surveys of risk factors in this context, see EVALUATING AIDS PREVENTION PROGRAMS: EXTENDED EDITION 293 (Susan L. Coyle et al. eds., 1991) (citation omitted) (“As the example of Mexican American and Anglo sexual behavior in Orange County illustrates, ‘homosexual’ and ‘bisexual’ relations may have a different meaning and expression for different ethnic groups living in the same community. Thus, to communicate effectively with people at risk, AIDS research and interventions must be sensitive to the variability of sexual meaning and experience within and among cultural groups.”). See also *id.* at 288 (discussing this study).

148. *Id.* at 19, 21.

involving people with substance use disorders via a gift card rather than cash to minimize the risk that the payments will be used on drugs or alcohol. Seddon noted that “the anxiety about cash incentive payments expressed by some stakeholders appeared to be quite specifically drug-related. Concern was rarely, if ever, expressed about the possibility of research participants using incentive payments to fund other illegal activity[.]”¹⁴⁹In practice, participants often convert gift cards into cash. But they do so at a loss.¹⁵⁰ Ultimately, participants end up with cash, but it is less than what they were promised for their study participation.¹⁵¹ Both findings present a justice problem while also disrespecting the autonomy and choices of particular individuals.¹⁵² Similarly, when gift cards are used for participant payment, researchers often gravitate to places like Target or Amazon. However, participants in a study in rural communities in Georgia revealed they commonly used study payments at the Dollar Store or KwikMart.¹⁵³ This information caused our research team to rethink its approach. We continue to learn from our participants: one participant, who lived in a multifamily dwelling, had her mailed card stolen, while another card was damaged in the mail. Each experience causes us to rethink how we can best meet our obligations to participants in a respectful and useful manner and informs how we can conduct and budget our research compensation in the future.

149. Toby Seddon, *Paying Drug Users to Take Part in Research: Justice, Human Rights and Business Perspectives on the Use of Incentive Payments*, 13 ADDICTION RSCH. & THEORY 101, 103 (2005) (citing Alison J. Ritter et al., *The Ethics of Reimbursing Injecting Drug Users for Public Health Research Interviews: What Price Are We Prepared to Pay?*, 14 INT’L J. DRUG POL’Y 1 (2003)).

150. Alexandra B. Collins et al., “*We’re Giving You Something So We Get Something in Return*”: *Perspectives on Research Participation and Compensation Among People Living with HIV Who Use Drugs*, 39 INT’L J. DRUG POL’Y 92, 96 (2017).

151. Seddon, *supra* note 149, at 103 (“A critical point about the exchange of vouchers is that when this occurs, whether the exchange is for cash or directly for drugs, interviewees usually receive less than the full value of the voucher. For example, the going rate in one research site for a £10 voucher was a £5 bag of heroin. In effect, this means that when vouchers are used in the drugs market, interviewees are ‘shortchanged’ and, furthermore, it is the drug sellers that are the beneficiaries of these ‘exchange rate’ costs.”); *see also* Collins et al., *supra* note 150, at 97 (“Consistent with Seddon (2005), participants shared how gift cards can create additional barriers (e.g., cannot access specific store, unable to purchase needed goods). As a result, they are often traded or sold for less than the original value, which can lead to inequities in compensation between those who likely have to trade gift cards (e.g., structurally vulnerable populations) and those who do not.”).

152. *See* Seddon, *supra* note 149, at 103–04 (discussing these concerns in terms of human rights).

153. Personal communication with Christy J.W. Ledford, Professor of Fam. Med., Vice Chair of Rsch., Dep’t of Fam. & Cmty. Med. & Curtis G. Hames, Distinguished Chair for the Dep’t of Fam. Med., Med. Coll. of Ga. at Augusta Univ., Dir., HamesNet (June 13, 2023). Other research demonstrates that participants appreciate greater flexibility in payment and that the mechanism of payment influences how they use it. *See, e.g.*, David S. Festinger & Karen L. Dugosh, *Paying Substance Abusers in Research Studies: Where Does the Money Go?*, 38 AM. J. DRUG & ALCOHOL ABUSE 43, 47 (2012) (“One possible explanation for the greater desirability and potency of case and check payments compared with gift certificates is that cash payments may provide greater flexibility in selection the choice of [reimbursement]. Rather than being restricted to using a gift card in a certain store or group of stores, cash and check payments may provide greater freedom to choose how the payments can be used.”).

As a member of an HIV/AIDS community advisory board, I was privileged to witness the power of community members whose perspectives are valued by the researchers with whom they were engaged.¹⁵⁴ The community members provided feedback about particular research approaches, the acceptability of certain procedures, and perspectives of research directions that drove decisions concerning which research was undertaken and how.¹⁵⁵ Similarly, as a member of Congressionally Directed Medical Research Program (“CDMRP”) peer reviews, I have seen scientific reviewers reconsider their evaluation of research applications after the consumer reviewers have articulated the strengths and weaknesses of the approach from the community perspective. These experiences prove the important and beneficial impact community input can have in research design and conduct.

To encourage more researchers to solicit this kind of community input into their research design, IRBs should pose questions about community engagement and its impact design.¹⁵⁶ More is required to stimulate the kind of community engagement needed to bring about the change required to implement justice in human subjects research. Too often, community engagement is consultative.¹⁵⁷ Researchers present their research questions and methods to select community members and solicit feedback.¹⁵⁸ But there is little room for community members to make meaningful changes to the direction of the research.¹⁵⁹ Ongoing, deep, and trusting community relationships only develop over time after sustained efforts are made to develop trust.¹⁶⁰ In communities where relationships are already strained and distrust is embedded, which often coincide with those that

154. For a discussion of effective HIV Community Advisory Boards (“CABs”), see Elliot R. Weinstein et al., *Promoting Health Equity in HIV Prevention and Treatment Research: A Practical Guide to Establishing, Implementing, and Sustaining Community Advisory Boards*, 10 THERAPEUTIC ADVANCES INFECTIOUS DISEASE 1, 3 (2023).

155. *Id.* at 8–11.

156. See Strauss et al., *supra* note 122, at 1210.

157. Tabet A. Brockman et al., *Community Engagement Strategies to Promote Recruitment and Participation in Clinical Research Among Rural Communities: A Narrative Review*, 7 J. CLINICAL & TRANSLATIONAL SCI. 84, 84 (2023) (“The most common levels of engagement were consultation.”).

158. Kathryn M. Stewart et al., *Community Advisory Boards: Experiences and Common Practices of Clinical and Translational Science Award Programs*, 3 J. CLINICAL & TRANSLATIONAL SCI. 218, 224 (2019) (“We found the percentage reporting that their CAB members have an advising role (84%) was higher than those reporting that CAB members provided strategic input (71%)”); see also Stella Safo et al., “*A Place at the Table*”: *A Qualitative Analysis of Community Board Members’ Experiences With Academic HIV/AIDS Research*, 16 BMC MED. RSCH. METHODOLOGY 80, 85 (2016) (highlighting a CAB member’s view that “[i]t’s this top down view of research as being ‘we’re going to do it on you and eventually we’re going to come up with really good programs but in the process we’re really not going to engage you’”).

159. Safo et al., *supra* note 158.

160. *Id.* at 86.

are underrepresented and sharing unequally in the benefits of research, the work will be that much more difficult.¹⁶¹

Researchers need to enter this work with humility because the scientific expertise they bring is not the only expertise of value. When undertaken in this spirit, community-based participatory research (“CBPR”)

recognizes the need for active cooperation between researchers and the community to drive research questions and produce pragmatic outcomes relevant to the needs of the community. A collaborative approach that equitably involves all partners in the research process, CBPR represents a ““democratization”“ of the research process by recognizing the unique strengths that each partner brings.¹⁶²

Of course, identifying the “community” can prove challenging. Differing views of the “community” have stopped studies or prevented them from going forward.¹⁶³ Views may differ within communities, but it is incumbent on researchers to solicit input from those who make up diverse communities to develop more inclusive research.¹⁶⁴

But researchers also cannot do this work alone. To sustain these efforts, they require support from funders and institutions.¹⁶⁵ But such efforts also need to be coordinated. Uncoordinated efforts can result in confusion and unduly burden community members if, for example, multiple researchers seek to engage the same community.¹⁶⁶ In such cases, the efforts can undermine the very relationships that the researchers seek to develop. Institutions look to build from existing relationships, informed by those researchers who laid the foundation.¹⁶⁷ In doing so, they should provide financial support and credit for those efforts,

161. *Id.* at 84–86.

162. Weinstein et al., *supra* note 154, at 2.

163. See, e.g., Jerome A. Singh & Edward J. Mills, *The Abandoned Trials of Pre-Exposure Prophylaxis for HIV: What Went Wrong?*, 2 PLOS MED. 234, 234 (2005) (describing HIV preexposure prophylaxis trials that were stopped in Cambodia and Cameroon, including complaints that “there was limited involvement of the target communities in the trial design”). The researchers provided their own explanation but acknowledged that, “[d]espite the establishment of these consultative mechanisms and our commitment to continue dialogue for the development of the study plans, we recognize that not all those who engaged with us felt a genuine sense of involvement—some individuals and organizations chose not to participate in meetings or community forums.” Kimberly Page-Shafer et al., *HIV Prevention Research in a Resource-limited Setting: The Experience of Planning a Trial in Cambodia*, 366 LANCET 1499, 1500 (2005); see also Leslie E. Wolf, *The Research Ethics Committee Is Not the Enemy: Oversight of Community-Based Participatory Research*, 5 J. EMPIRICAL RSCH. ON HUM. RSCH. ETHICS 77, 79–80 (2010) (describing differences in definition of “community” in a specific CBPR study and noting that “[c]ommunity may be defined in many ways, such as geography, race or ethnicity, culture, gender, activities, and interests” and that “we are all members of multiple, sometimes overlapping, communities”).

164. See Kimberly Page-Shafer et al., *supra* note 164, at 1502.

165. Diane C. Calleson et al., *Community-Engaged Scholarship: Is Faculty Work in Communities a True Academic Enterprise?*, 80 ACAD. MED. 317, 320 (2005).

166. *Id.* at 317, 319.

167. *Id.* at 319–20.

given the fruits of those efforts may not achieve realization for years.¹⁶⁸ Similarly, funders should provide sustained funding for community engagement that can extend beyond any investigator-initiated project. New funding mechanisms may be needed.

2. Increasing Representation with IRBs

The regulatory requirements regarding the composition of IRBs reflect a commitment to representation.¹⁶⁹ While professional competence to conduct reviews is critical, the regulation regarding the composition of the IRB also speaks to the diversity of the members with respect to “race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.”¹⁷⁰ Arguably, this goal is supported by the requirements that the IRB include “at least one member whose primary concerns are in nonscientific areas” and “at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.”¹⁷¹

IRB membership has not lived up to these stated goals. Multiple studies report that IRB composition is largely White.¹⁷² Although these studies are over a decade or more old, these findings likely still ring true as it is primarily academic medical center and university faculty who serve on IRBs, and those faculty are primarily White and male.¹⁷³ Accordingly, most IRBs do not

168. For a discussion of some of the institutional barriers to community-engaged research, see, e.g., Marissa Bell & Neil Lewis Jr., *Universities Claim to Value Community-Engaged Scholarship: So Why Do They Discourage It?*, 32 PUB. UNDERSTANDING SCI. 304 (2023); Diane C. Calleson et al., *supra* note 165, at 317; David G. Marrero et al., *Promotion and Tenure for Community-Engaged Research: An Examination of Promotion and Tenure Support for Community-Engaged Research at Three Universities Collaborating Through a Clinical and Translational Science Award*, 6 CLINICAL & TRANSLATIONAL SCI. 204, 207 (2013).

169. See 45 C.F.R. § 46.107(a).

170. *Id.* (“Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.”).

171. 45 C.F.R. § 46.107(b)–(c).

172. William C. Rencher & Leslie E. Wolf, *Redressing Past Wrongs: Changing the Common Rule to Increase Minority Voices in Research*, 103 AM. J. PUB. HEALTH 2136, 2138–39 (2013) (citing examples of such studies).

173. See *supra* Section II.B.

adequately represent the diversity of their communities.¹⁷⁴ Additionally, as originally conceived, the regulatory requirement for one community member (i.e., the nonaffiliated member) would represent one-fifth of the total membership of five.¹⁷⁵ But IRBs are often much larger than five and have not expanded their community representation as they have grown.¹⁷⁶

These structural factors undoubtedly influence IRB decision making. Not only do they cause IRBs to fail to reap the benefits of diverse voices, but research suggests that community members may feel reluctant to speak when they are the sole voice.¹⁷⁷ My own experience on an IRB and other committees is consistent with these findings; I have seen scientific members dismiss community members' contributions, suggesting that they do not understand the science when they raise questions. But my experience also suggests that such outcomes are not inevitable. The CDMRP peer review process provides specific training to its consumer reviewers that emphasizes their importance.¹⁷⁸ In my experience, it also places the consumer reviewer second, which gives greater power to the consumer voice and signals importance.¹⁷⁹

Failure of IRB membership to reflect the diversity of a community can also undermine IRBs' credibility. When I served on the UCSF IRB, we reviewed an amendment for a CBPR proposal that involved an investigation of the sale of loose cigarettes in a predominantly Black neighborhood in San Francisco.¹⁸⁰ The

174. *See supra* Section II.B.

175. NAT'L BIOETHICS ADVISORY COMM'N, 1 ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS 62–64 (2001) (including Recommendation 3.10 that members who are unaffiliated with institution and whose primary concern are in nonscientific areas “should collectively represent at least 25 percent of the Institutional Review Board membership”).

176. *Id.*; *see also* Sohini Sengupta & Bernad Lo, *The Roles and Experiences of Nonaffiliated and Non-Scientist Members of Institutional Review Boards*, 78 ACAD. MED. 212, 217 (2003).

177. Charles W. Lidz et al., *The Participation of Community Members on Medical Institutional Review Boards*, 7 J. EMPIRICAL RSCH. ON HUM. RSCH. ETHICS 1, 6–7 (2012); Robert Klitzman, *Institutional Review Board Community Members: Who Are They, What Do They Do, and Whom Do They Represent?*, 87 ACAD. MED. 975, 975 (2012); *see generally* Sengupta & Lo, *supra* note 176, at 216–17 (“At the group level, IRB chairs and staff can change the group culture to help non-scientist and nonaffiliated members feel that they are heard and that their opinions are respected.”).

178. *Frequently Asked Questions*, DEP'T OF DEF. CONGRESSIONALLY DIRECTED MED. RSCH. PROGRAMS (Sept. 1, 2022), <https://cdmrp.health.mil/CWG/role.aspx>.

179. *Consumer Involvement*, DEP'T OF DEF. CONGRESSIONALLY DIRECTED MED. RSCH. PROGRAMS, <https://cdmrp.health.mil/CWG/role.aspx> (last visited Dec. 16, 2023) (“Consumers represent the collective views of survivors, patients, family members, and persons affected by and at risk for certain conditions, diseases or injuries They participate as a full member of the review panel, with full voting member status.”); DEP'T OF DEF. CONGRESSIONALLY DIRECTED MED. RSCH. PROGRAMS, CONSUMER BROCHURE 1 (2016), https://cdmrp.health.mil/cwg/docs/Consumer_Brochure.pdf (“The unique voices and experiences of survivors and their families have been a pivotal part of the Congressionally Directed Medical Research Programs (CDMRP) since 1993 As a result of our efforts to include consumers in the scientific review of research proposals, doors are opening across the nation.”).

180. Ruth E. Malone et al., *“It's Like Tuskegee in Reverse”: A Case Study of Ethical Tensions in Institutional Review Board of Community-Based Participatory Research*, 96 AM. J. PUB. HEALTH 1914,

community partners identified the sale of loose cigarettes, an illegal practice under state law, as problematic because it undermined efforts at smoking cessation.¹⁸¹ The IRB approved an observational study that included observation of loose cigarette sales.¹⁸² However, when the researchers sought approval to amend the protocol based on community feedback to include attempts to purchase loose cigarettes, the IRB refused.¹⁸³

Community research partners felt betrayed by the IRB's rejection. In their view, the IRB chose to protect "community predators" over the health of the community itself. This seemed a bitter irony. "It's like Tuskegee in reverse," commented one community member, referring to the infamous research in which African American men with syphilis were studied—but not treated—long after a definitive cure for the disease had been discovered.¹⁸⁴

The researchers' article about their experiences with this study makes clear that the community not only did not feel heard or respected, but rather, felt betrayed by the system.¹⁸⁵ When the community partners attended the IRB meeting to discuss the amendment, they "would have seen few [IRB] members that looked like them."¹⁸⁶ The data demonstrate that the lack of diversity on the IRB was not limited to UCSF, nor has the makeup changed significantly in the almost twenty years since the Protecting the 'Hood Against Tobacco study.¹⁸⁷

IRBs have an obligation to increase the representativeness of their membership.¹⁸⁸ Yet, it is important to recognize the challenges they face in achieving this goal. When looking at faculty representation, for example, faculty from historically marginalized and minoritized communities are already overburdened with potentially negative career impacts.¹⁸⁹ Because they are underrepresented in faculties generally, the same faculty are asked to serve on multiple committees to fulfill representation goals.¹⁹⁰ Moreover, IRB service is

1914–15 (2006); *see also* Wolf, *supra* note 163, at 77 ("[T]his article . . . build[s] on the . . . Malone et al. case study by providing some perspectives from the [research ethics committee] side.").

181. Malone et al., *supra* note 180, at 1915.

182. *Id.* at 1916.

183. *Id.* at 1916–17; Wolf, *supra* note 163, at 78–79.

184. Malone et al., *supra* note 180, at 1917.

185. *Id.*

186. Wolf, *supra* note 163, at 81; Jessica Ball & Pauline Jaynst, *Enacting Research Ethics in Partnerships with Indigenous Communities in Canada: "Do It in a Good Way,"* 3 J. EMPIRICAL RSCH. ON HUM. RSCH. ETHICS 33 (2008).

187. *See* BERRY ET AL., *supra* note 50, at 22.

188. José E. Rodríguez et al., *Addressing Disparities in Academic Medicine: What of the Minority Tax?*, 15 BMC MED. EDUC. 1, 3–4 (2015) (explaining how a lack of diverse faculty at medical institutions negatively impacts research on minority health care needs, limits mentors for minority students, and reduces exposure to underserved populations).

189. *Id.* at 2; Virginia Gewin, *The Time Tax Put on Scientists of Colour*, 583 NATURE 479, 481 (2020).

190. Gewin, *supra* note 189, at 479–81.

a particular heavy service requirement that infringes on faculty research time.¹⁹¹ Heavy service loads are identified as a detriment to promotion and tenure.¹⁹² Strategies need to be identified to increase representation without these detrimental effects. Restricting service to those who have achieved certain career milestones, such as tenure or independent investigator status, can minimize negative career impacts. Limiting other service responsibilities while serving on the IRB might also reduce the burden on faculty. Additionally, compensating members for their efforts would recognize the value of the work and opportunity costs of serving.

Creative thinking to improve community engagement and encourage greater participation as nonscientific IRB members is also needed.¹⁹³ IRBs often confront challenges in identifying community members in general.¹⁹⁴ One potential approach to identifying members is to tap into existing partnerships. Community-based research partnerships are an appropriate place to begin; community partners already recognize the value of research and have some positive relationships with the institution. But other community relationships, alumni networks, admissions networks, and service work may prove fruitful places to build relationships that could provide a sustained pool of IRB members. Recruitment should not be the end of the efforts, either. As discussed above,¹⁹⁵ community members often feel silenced in IRB meetings, but IRBs can take steps to empower community members. IRBs should provide sufficient training so that nonscientific reviewers feel competent to apply the regulations to the protocols they review, but also feel empowered by appreciating the unique role they play. IRBs should also structure the review process and provide training to their scientific reviewers so that the contributions of nonscientific reviewers are valued as they deserve. The HIV CAB and CDMRP models demonstrate this is an achievable goal.¹⁹⁶

C. Increasing Representation Among Researchers

Multiple, complex factors contribute to the underrepresentation of historically minoritized populations among researchers. Access to education is not distributed equally within society—with lingering effects from de jure and

191. See *id.* at 479 (noting that serving on diversity committees takes time from research responsibilities).

192. See *id.* at 481 (stating that sitting on diversity committees can lower productivity and slow career progression).

193. Rencher & Wolf, *supra* note 172, at 2138–39.

194. Robert Klitzman, *Institutional Review Board Community Members: Who Are They, What Do They Do, and Whom Do They Represent?*, 87 ACAD. MED. 975, 977 (2012).

195. See generally Sengupta & Lo, *supra* note 176, at 216–17 (noting that IRB meetings may be intimidating to community members); Lidz, *supra* note 177, at 5–7 (explaining that community members were less active in their secondary reviewer roles than other members).

196. See *supra* notes 154–58, 176–79 and accompanying text.

de facto segregation and funding challenges.¹⁹⁷ Within the school system, disparities persist in who is selected for advance coursework and who is targeted for punishment, with implications for academic advancement.¹⁹⁸ Even those who successfully navigate those barriers may feel alienated and isolated, experience self-doubt, lack role models and mentors, face questions about their qualifications, or experience discrimination.¹⁹⁹

There have been concerted efforts to increase diversity within the biomedical workforce, both within the government and within individual institutions.²⁰⁰ However, given its prominence in biomedical research funding and its national reach,²⁰¹ this Section focuses on NIH's efforts. NIH dedicates a webpage to documenting its commitment to and efforts in promoting diversity in biomedical research.²⁰² It ties this commitment to its core mission of advancing "knowledge to enhance health, lengthen life, and reduce illness and disability" and notes how diversity improves research and is therefore critical to that mission.²⁰³ With respect to diversity, NIH discusses underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women.²⁰⁴ NIH's diversity efforts came from its own initiatives and directives from Congress.²⁰⁵ Its website states, "[f]or example, in 1992, Congress approved a proposal by the NIH Director to assess all minority-targeted training support mechanisms," which documented the underrepresentation of minorities across the research enterprise.²⁰⁶ As NIH notes, Congress has taken multiple steps supporting the NIH's diversity

197. JARED BASS ET AL., U.S. DEP'T OF EDUC., *ADVANCING DIVERSITY AND INCLUSION IN HIGHER EDUCATION: KEY DATA HIGHLIGHTS FOCUSING ON RACE AND ETHNICITY AND PROMISING PRACTICES* 1–2, 17 (2016).

198. *Id.* at 17–18; Travis Riddle & Stacey Sinclair, *Racial Disparities in School-Based Disciplinary Actions are Associated with County-Level Rates of Racial Bias*, 116 PNAS 8255, 8255 (2019).

199. BASS ET AL., *supra* note 197, at 47; Swartz et al., *supra* note 45, at S34–36.

200. *See* BASS ET AL., *supra* note 197, at 38–39; *Diversity Initiatives*, OFF. OF THE DIR., NAT'L SCI. FOUND., <https://www.nsf.gov/od/oecr/diversity.jsp> (last visited Dec. 16, 2023).

201. *Grants & Funding*, NAT'L INSTS. OF HEALTH, <https://www.nih.gov/grants-funding> (last visited Dec. 16, 2023).

202. *Diversity in Extramural Program*, NAT'L INSTS. OF HEALTH, <https://extramural-diversity.nih.gov/index> (last visited Dec. 16, 2023).

203. *Diversity Matters*, NAT'L INSTS. OF HEALTH, <https://extramural-diversity.nih.gov/diversity-matters> (last visited Dec. 16, 2023).

204. *Id.*

205. *Eliminating Barriers – Congressional Interest in Diversity*, NAT'L INSTS. OF HEALTH, <https://extramural-diversity.nih.gov/building-participation/eliminating-barriers> (last visited Dec. 16, 2023); *see also Building Participation*, NAT'L INSTS. OF HEALTH, <https://extramural-diversity.nih.gov/building-participation> (last visited Dec. 16, 2023) (noting internal efforts include establishment of Division of Biomedical Research Workforce in 2015 and Office for Scientific Workforce Diversity and related committees).

206. *Eliminating Barriers – Congressional Interest in Diversity*, *supra* note 205.

efforts.²⁰⁷ Specific directives include Section 402(h) of the Public Health Service Act, which provides:

The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the field of biomedical and behavioral research.²⁰⁸

Congress also enacted the Minority Health and Health Disparities Research and Education Act of 2000, which established the National Center on Minority Health and Health Disparities at NIH.²⁰⁹ In doing so, Congress acknowledged the “continuing disparities in the burden of illness and death experienced by African Americans, Hispanics, Native Americans, Alaska Natives, and Asian Pacific Islanders, compared to the United States population as a whole.”²¹⁰ Further, Congress recognized the “national need for minority scientists in the fields of biomedical, clinical, behavioral, and health services” and that “underrepresented minorities and women in the scientific, technological, and engineering workforce enable society to address its diverse needs.”²¹¹ Congress also directed federal agencies to “expand or add programs that effectively overcome barriers” to successful transitions.²¹² NIH additionally points to language in the American Innovation and Competitiveness Act of 2017²¹³ and the 21st Century Cures Act²¹⁴ as supporting its diversity efforts.²¹⁵ These efforts are also supported by civil rights laws that prohibit discrimination based on sex, race, ethnicity, or disability.²¹⁶ NIH implemented programs at every level, including precollege resources, precollegiate and collegiate funded research experiences, collegiate, predoctoral, and postdoctoral research training and education, scholarships, predoctoral and postdoctoral fellowships, scholars programs, research support, loan repayment programs and career support through a number of mechanisms.²¹⁷

207. *Id.*

208. 42 U.S.C. § 282(h).

209. Pub. L. No. 106-525, 114 Stat. 2496 (2000).

210. *Id.* § 2(1).

211. *Id.* § 2(3), (7).

212. *Id.* § 2(9).

213. Pub. L. No. 114-329, 130 Stat. 2969 (2016).

214. Pub. L. No. 114-255, 130 Stat. 1033 (2016).

215. *Underrepresented Racial and Ethnic Groups*, NAT’L INSTS. OF HEALTH, <https://extramural-diversity.nih.gov/diversity-matters/underrepresented-groups> (last visited Dec. 16, 2023).

216. *Eliminating Barriers – Congressional Interest in Diversity*, *supra* note 205.

217. *Career Pathways*, NAT’L INSTS. OF HEALTH, <https://extramural-diversity.nih.gov/career-pathways> (last visited Dec 16, 2023).

Despite these efforts, additional work is required.²¹⁸ That work likely has been made more difficult, but not impossible, by the Supreme Court's decision in *Students for Fair Admissions, Inc. v. Presidents and Fellows of Harvard College*.²¹⁹ That decision limits the use of race in undergraduate admissions, but the full scope of its implications is yet to come. In the immediate wake of the decision, many are speculating as to whether it will apply to graduate and professional school admissions (likely) and to employment (less clear)²²⁰ and exploring alternative paths to achieve diversity goals.²²¹

218. Swartz et al., *supra* note 45, at S36; *see also* Section I.B.

219. 600 U.S. 181 (2023); Lindsay F. Wiley et al., *Eliminating Racism in Health Care Before and After the Supreme Court's Affirmative Action Decision*, HEALTH AFFS. FOREFRONT (July 7, 2023), <https://www.healthaffairs.org/forefront/eliminating-racism-health-care-before-and-after-supreme-court-s-affirmative-action>.

220. *See, e.g.*, Olympia Duhart, *Supreme Court's Affirmative Action Decision Will Shrink an Already Narrow Pipeline to the Legal Profession*, DIVERSE ISSUES IN HIGHER EDUC. (July 2, 2023), <https://www.diverseeducation.com/opinion/article/15541631/supreme-courts-affirmative-action-decision-will-shrink-an-already-narrow-pipeline-to-the-legal-profession> (discussing how law school admissions, which already favor White male students, will further skew away from applicants who are people of color); Stephanie Saul, *With End of Affirmative Action, a Push for a New Tool: Adversity Scores*, N.Y. TIMES (July 2, 2023), <https://www.nytimes.com/2023/07/02/us/affirmative-action-university-of-california-davis.html> (explaining how recent Supreme Court decision will likely cause a decrease in an already low number of practicing Black doctors due to medical school barriers); Andrew Ross Sorkin et al., *Why Corporate America Is Worried About Affirmative Action*, N.Y. TIMES (June 30, 2023), <https://www.nytimes.com/2023/06/30/business/dealbook/corporate-diversity-affirmative-action.html> (arguing that effects of this Supreme Court ruling will not only affect higher education, but also initiatives to build a more diverse, equitable, and inclusive workforce in corporate America); Trisha Thadani, *Affirmative Action Ruling Could be a Blow to Diversity in Tech*, WASH. POST (July 4, 2023) (warning that Supreme Court ruling could produce a negative effect on Silicon Valley companies' hiring practices and diversity commitments). *But see* Erin Connell et al., *U.S. Supreme Court Decision Does Not Foreclose Legally Compliant DEI Initiatives in Corporate America*, CORP. COUNS. (July 6, 2023, 10:51 AM), <https://www.law.com/corpocounsel/2023/07/06/u-s-supreme-court-decision-does-not-foreclose-legally-compliant-dei-initiatives-in-corporate-america/> (advising that while results of decision will impact corporate Diversity, Equity, and Inclusion programs, it does not necessitate a direct legal impact because employers could already not consider race in employment decision making).

221. *See, e.g.*, Tiffany González, *The Path Forward for Affirmative Action*, WASH. POST (July 1, 2023), <https://www.washingtonpost.com/made-by-history/2023/07/01/affirmative-action-texas-supreme-court/> (discussing legislative action as an alternative for achieving diversity goals by examining Texas's Top 10 Percent Plan); Lawrence H. Summers, *The Affirmative Action Ruling is Big. Now Elite Colleges Need to Think Bigger*, WASH. POST (July 1, 2023), <https://www.washingtonpost.com/opinions/2023/07/01/lawrence-summers-affirmative-action-elite-colleges/> (urging higher education institutions to take action in addressing diversity issues by eliminating legacy applicant preferences, considering family disadvantage in selecting applications, and creating programs for disadvantaged kids and public school teachers); Saul, *supra* note 220 (discussing use of a race-neutral "adversity score" that takes into account socioeconomic factors as an alternative to affirmative action in medical school admission applications); Richard Arum & Mitchell L. Stevens, *For Most College Students, Affirmative Action Was Never Enough*, N.Y. TIMES (July 3, 2023), <https://www.nytimes.com/interactive/2023/07/03/opinion/for-most-college-students-affirmative-action-was-not-enough.html> (arguing that key to racial equality in higher education is to invest in and elevate quality of less selective middle and lower tier colleges); Caren Ulrich Stacy et al., *A Call to Action: Stay Calm and Carry On (Legally) in the Wake of Anti-DEI Directives*, AM. LAW. (June 30, 2023), <https://www.law.com/americanlawyer/2023/06/30/a-call-to-action-stay-calm-and-carry-on-legally-in->

The research community needs to continue to be creative and overcome the barriers that remain, including the potential barriers imposed by the Supreme Court’s decision. As demonstrated in Part II,²²² there are multiple documented reasons for continuing to invest in these efforts—ones that Congress previously supported.

My own work on developing a diverse pipeline for bioethics confirms that we need to reach students early—before career choices are made.²²³ These students may have never met a researcher or know the impact researchers can have. As Marian Wright Edelman said, “It’s hard to be what you can’t see.”²²⁴ Teaching examples of successful, diverse researchers who impacted their communities can provide powerful inspiration and influence over career choices.²²⁵ But inspiration is not enough. For a variety of reasons, diverse students are less likely to complete their degrees than White students.²²⁶ This gap is not inevitable. Georgia State is one of the most diverse colleges in the United States and eliminated undergraduate graduation gaps based on race, ethnicity, or low income.²²⁷ It achieved this success by using predictive analytics to identify all educationally or financially at risk students, regardless of background, coupled with early, intensive student support, tutoring, mentoring, and microgrants.²²⁸ That kind of support needs to continue throughout graduate

the-wake-of-anti-dei-directives/ (urging organizations to perform an “audit” of their DEI initiatives, amplify or modify these initiatives accordingly if there are gaps in representation, hiring, pay, and advancement opportunities); Demetria D. Frank et al., *Affirmative Action and the Myth of Merit*, INSIDE HIGHER ED (July 5, 2023), <https://www.insidehighered.com/opinion/views/2023/07/05/affirmative-action-and-myth-merit-opinion> (arguing that higher education institutions should redefine acceptance on basis of merit to include context of an individual’s circumstances and in relation to their starting point and obstacles they have overcome).

222. See *supra* Part II.

223. *Make Room, the Next Generation Is Bringing Bioethics to the Table*, GREENWALL FOUND., <https://greenwall.org/news/make-room-the-next-generation-is-bringing-bioethics-to-the-table> (last visited Oct. 10, 2023); Leslie E. Wolf et al., *Engaging Diversity: A New Approach to Bioethics Teaching*, 8 VOICES BIOETHICS 1, 2 (2022).

224. Marian Wright Edelman, *It’s Hard to Be What You Can’t See*, CHILD WATCH COLUMN (Aug. 21, 2015), <https://www.childrensdefense.org/child-watch-columns/health/2015/its-hard-to-be-what-you-cant-see/>.

225. Wolf et al., *supra* note 223, at 3, 6.

226. BASS ET AL., *supra* note 197, at 6, 17–18, 24–28.

227. COMPLETE COLL. GA., 2018 STATUS REPORT, GEORGIA STATE UNIVERSITY 5 (2018); see also Richard Fausset, *Georgia State, Leading U.S. in Black Graduates, Is Engine of Social Mobility*, N.Y. TIMES (May 15, 2018), <https://www.nytimes.com/2018/05/15/us/georgia-state-african-americans.html>; Beth McMurtrie, *Georgia State U. Made Its Graduation Rate Jump. How?*, CHRONICLE OF HIGHER EDUC. (May 25, 2018), <https://www.chronicle.com/article/georgia-state-u-made-its-graduation-rate-jump-how/>.

228. McMurtrie, *supra* note 227; Ellie Hensley, *GSU Gets \$1.2 Million in Grants to Expand Freshman Transition Program*, ATLANTA BUS. CHRON. (Dec. 17, 2015), <https://www.bizjournals.com/atlanta/news/2015/12/17/gsu-gets-1-2-million-in-grants-to-expand-freshman.html>; Sara Weissman, *Clearing the ‘Final Obstacle’ to a Degree*, INSIDE HIGHER ED (Apr. 4,

education, post-graduation training, and early career development to avoid losing those we inspire to enter the research pipeline. Such efforts will also foster a multiplier effect within the research enterprise; that is, as we diversify the research pipeline, we will also diversify the pool of those eligible to serve as peer reviewers, IRB members, and leaders within the research community.

V. CONCLUSION

In short, everyone within the research community has an obligation to do everything possible within their own sphere to advance equitable research.²²⁹ The well-documented inequities in biomedical research and health care are long standing,²³⁰ but change is possible. The research community must harness the attention to social justice that our recent experiences with the pandemic, a racial reckoning, economic crises, climate crises, and other events have evoked.²³¹ Such attention within the research enterprise can not only lead to more equitable research and greater health equity, but potentially to advance greater equity in society.

2022), <https://www.insidehighered.com/news/2022/04/05/new-report-assesses-georgia-states-microgrant-program>.

229. *See supra* Part IV.

230. *See supra* Part II; Section III.B.

231. *See supra* Part I.