Applying Civil Rights Law to Clinical Research: Title VI's Equal Access Mandate

Joseph Liss, David Peloquin, Mark Barnes, and Barbara E. Bierer

Keywords: Discrimination, Equal Protection, Clinical Trials, Title VI, and Enforcement

Abstract: Title VI of the Civil Rights Act of 1964 and its implementing regulations prohibit federally-funded educational institutions and healthcare centers from engaging in disparate impact discrimination "on the ground of race, color, or national origin" in all of their operations.

Minority communities have long faced both limited opportunities to enroll in cutting edge clinical research and concerns about whether their rights as research subjects are adequately respected.[1] A recent examination of vaccine clinical trials from 2011 to 2020 found Black and African American individuals were underrepresented by 2-3 percentage points and Hispanic and Latino individuals by more than 5 percentage points, compared to the U.S. population.[2] Data from the FDA found Black and African American participation was even lower, making up only 8 percent of clinical trial enrollment for new molecular entities and therapeutic biologics approved in 2020.[3] Both the National Institutes of Health (NIH) and Food and Drug Administration (FDA) have, in recent years, strongly encouraged the inclusion of racial and ethnic minorities in clinical research, and both require the submission of certain breakdowns of data by race and other variables.[4] For example, in response to the COVID-19 pandemic, NIH launched the "Rapid Acceleration of Diagnostics (RADx)" program and specifically the "RADx- Underserved Populations (RADx-UP)" initiative with the goal of understanding disparities in the morbidity and mortality of COVID-19, establishing community research sites, encouraging collaboration, and evaluating novel testing strategies."[5] The FDA's "Enhance EQUITY Initiative" shares similar goals.[6] Encouraging access across diverse individuals creates participation opportunities for marginalized communities and improves the generalizability of research results.

Joseph Liss, J.D., M.P.P., *was an associate in the health care group of Ropes & Gray LLP in New York, New York, USA. Previously, he was a Legal Fellow at the Multi-Regional Clinical Trials Center of the Brigham and Women's Hospital and Harvard.* **David Peloquin, J.D.,** *is a partner at Ropes & Gray LLP in Boston, Massachusetts, USA. He focuses his practice on advising academic medical centers, life sciences companies, and information technology companies on issues related to human subjects and animal research, data privacy, and general health care compliance. He is a senior advisor to the Multi-Regional Clinical Trials Center* (Continued on page 102)

The Journal of Law, Medicine & Ethics, 50 (2022): 101-108. © 2022 The Author(s)
DOI: https://doi.org/10.1017/jme.2022.14

However, the Department of Health and Human Services (HHS), of which NIH is a constituent part, has not used the full arsenal of legal and policy tools at its disposal to push for equal access. In particular, we argue that Title VI of the Civil Rights Act of 1964, which is enforced by HHS's Office for Civil Rights (OCR), obligates institutions that receive Federal financial assistance and host clinical research to provide equal access to participation in clinical trials to racial and ethnic minority communities. We first consider the ban on discrimination that Title VI created, including the scope of its application. We next discuss the unique challenges of applying Title VI in the clinical research context and how those challenges may be overcome. Finally, we discuss questions of implementation and enforcement.

The Department of Health and Human Services (HHS), of which NIH is a constituent part, has not used the full arsenal of legal and policy tools at its disposal to push for equal access. In particular, we argue that Title VI of the Civil Rights Act of 1964, which is enforced by HHS's Office for Civil Rights (OCR), obligates institutions that receive Federal financial assistance and host clinical research to provide equal access to participation in clinical trials to racial and ethnic minority communities.

Title VI's Scope of Application

Title VI bans discrimination by recipients of certain government funding on the basis of race, color, and national origin. HHS regulations have extended this ban to cover disparate impact discrimination, including the unintentional mistreatment of individuals of differing racial and ethnic backgrounds. Congress has made clear that Title VI applies quite broadly, especially in the health care context, to all operations of hospitals and universities.

Title VI prohibits recipients of Federal financial assistance from conducting activities that have a disparate impact on those of any particular race, color, or national origin. Section 601 of Title VI prohibits intentional discrimination "on the ground of race, color, or national origin ... under any program or activity receiving Federal financial assistance."[7] While intentional discrimination can be difficult to prove,[8] Section 602 of Title VI permits agencies authorized to administer grants to issue regulations to "effectuate the provisions" of Section 601.[9] HHS used its Section 602 authority to prohibit recipients of Federal financial assistance from "utilize[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin."[10] The Department of Justice (DOJ) and HHS OCR wrote in recent guidance that "[d]isparate impact discrimination focuses on the consequences of a recipient's practices rather than the motivation, and occurs when a recipient has an otherwise neutral policy or practice that has a disproportionate and adverse effect on individuals of a certain race, color, or national origin .... "[11] The Supreme Court, since the 1970s, has recognized the effect of HHS's regulations prohibiting disparate impact discrimination.[12]

Importantly, while individuals may bring claims under Section 601, only the government may bring disparate impact claims. In *Alexander v. Sandoval*, the Supreme Court held that a class of non-English speakers could not bring, under DOJ's regulations imple-

(Continued from page 101) *of BWH and Harvard.* **Mark Barnes, J.D., L.L.M,** *is a partner at Ropes & Gray LLP in Boston, Massachusetts, USA. His law practice focuses on human and animal research, stem cell and genetic research, research grants and contracts, research fraud/research misconduct, and international research. He co-founded and serves as the faculty co-director of the Multi-Regional Clinical Trials Center of BWH and Harvard. Mr. Barnes formerly served at Harvard as the Senior Associate Provost and University Senior Research Officer; started and directed Harvard's HIV/AIDS treatment programs in Nigeria, Tanzania and Botswana; and has held senior appointed positions in the New York City and State departments of health.* **Barbara E. Bierer, M.D.,** *a hematologist-oncologist, is Professor of Medicine at Harvard Medical School and the Brigham and Women's Hospital in Boston, Massachusetts, USA. Dr. Bierer co-founded and serves as faculty director of the Multi-Regional Clinical Trials Center of BWH and Harvard, a research and policy center focused on the ethics, conduct, and regulatory environment of global clinical trials. In addition, she is the Director of the Regulatory Foundations, Ethics, and Law program at the Harvard Clinical and Translational Science Center and Director of Regulatory Policy for SMART IRB.*

The Journal of Law, Medicine & Ethics, 50 (2022): 101-108. © 2022 The Author(s)

menting Section 602, a challenge to Alabama's decision to administer state driver's license examinations only in English; DOJ's regulations, like those from HHS, prohibit disparate impact discrimination.[13] The practical result of this decision is that nearly all Title VI enforcement requires government action, as "few federally funded programs are overtly discriminatory and, as a result, intentional race and national origin discrimination have become increasingly difficult to prove."[14]

Congress has made clear that Title VI applies to all of the operations of many entities, such as hospitals and universities, that receive Federal financial assistance and, thus, to the conduct of their clinical trials. As originally passed, Title VI applied to "any program or activity receiving Federal financial assistance."[15] In response to a 1984 Supreme Court ruling holding that similar language in Title IX applied only to the portion of the institution that receives federal funding,[16] Congress, in the Civil Rights Restoration Act of 1987 (CRRA), amended Title VI to clarify that it applies to all the activities of an institution receiving Federal financial assistance.[17] Congress defined "program or activity" broadly to include "all the operations of … a college, university, or other postsecondary institution" and "all the operations of … an entire corporation, partnership or other private organization … which is principally engaged in the business of providing education [or] health care …. "[18] HHS later added that definition to its regulations implementing the CRRA.[19]

Congress has defined Federal financial assistance broadly to include assistance provided "by way of grant, loan, or contract other than a contract of insurance or guaranty … "[20] That definition sweeps in Medicare Part A (primarily inpatient Medicare spending), Medicaid, and NIH grants, meaning that nearly every hospital and research university must comply with Title VI.[21] In its regulations implementing the CRRA, HHS explained that, "if a college or university receives Federal financial assistance from the Department to support medical research, all of the operations of the college or university are covered, not solely the operations of the component performing the medical research."[22] Similarly, all of the operations of a private hospital receiving Federal financial assistance are covered.[23] Further, recent rulemaking implementing Section 1557 of the Affordable Care Act (ACA) has mirrored the CRRA's language.[24] However, Title VI's protections would not extend to an entity that conducts research only on behalf of private industry, although industry-funded trials at healthcare organizations would still be subject to Title VI through enforcement against the hospital. Thus, if a healthcare provider at a community hospital with Medicare-covered patients conducted a clinical trial without any external funding, her research would still be subject to Title VI.

HHS regulations and NIH guidance require NIH grant recipients to comply with Title VI as a condition of receiving grant funding, a contract-like compliance mechanism. HHS regulations require that potential awardees of Federal financial assistance provide a one-time assurance of compliance with Title VI,[25] known as Form HHS 690.[26] While the form specifies only that the applicant will comply with Title VI for "any program or activity for which the Applicant receives Federal financial assistance from the Department,"[27] it is "filed for the organization and is not required for each application," according to NIH,[28] suggesting its institution-wide reach. Much like other NIH assurances, this is a contract-like document that federal officials interpret as imposing obligations upon the signatory to "comply with: Title VI of the Civil Rights Act of 1964 …. "[29]

In summary, Title VI prohibits intentional discrimination, and HHS has used its authority under Section 602 of Title VI to prohibit disparate impact discrimination. Congress has made clear that Title VI's reach is extensive, covering all operations of many hospitals, community health centers, and universities, at which a substantial portion of domestic clinical research occurs. However, both researchers and government officials have paid little attention to how Title VI applies in the research context. It is to these implementation issues that we now turn.

Implementation Issues in the Clinical Trial Context

Congress designed Title VI to provide expansive protections that mandate equal access to participation in programs established by federally-funded entities. However, only the government may enforce disparate impact discrimination claims, and Title VI and HHS's implementing regulations permit justified deviations from equal access; courts and the DOJ evaluate such issues under a burden-shifting framework borrowed from Title VII employment discrimination cases.[30] Further, a lack of enforcement has, to date, blunted the effectiveness of Title VI in the research context.

One may argue that clinical trials testing interventions in clinical equipoise provide no anticipated clinical benefit to participants, and, thus, failing to provide equal access to clinical trials does not harm affected individuals. However, Title VI, itself, provides a response. Title VI separately specifies that individuals may neither "be excluded from participation in,"

The Journal of Law, Medicine & Ethics, 50 (2022): 101-108. © 2022 The Author(s)

nor "be denied the benefits of" any "program or activity receiving Federal financial assistance."[31] Understanding the phrase "participation in" narrowly – so as to mandate that individuals receive Title VI protection only if they actually benefit from the service they receive – would render the phrase "participation in" superfluous; courts generally reject the idea that Congress includes surplus language in its laws.[32] This so-called rule against superfluity is so common that even its detractors have admitted it is "widely recognized."[33]

Further, clinical trials often provide direct benefits. A patient suffering from cancer or a rare genetic condition may be able to receive cutting edge treatments only through participation in such trials, creating direct – and perhaps substantial – benefits for those who have failed other treatments or when no treatment exists. Individuals derive additional benefits from contributing to scientific knowledge and from assisting future generations or others in their communities. Of note, Title VI provides no right to participate in any particular clinical trial; rather, once an institution elects to offer a clinical trial, the institution must offer the opportunity to participate in the study on equal terms, protecting against disparate impact on individuals of differing racial and ethnic backgrounds.

By way of example, Title VI prohibits selecting sites at which recipients of Federal financial assistance offer programs, such as clinical services, so as to impact disparately protected classes.[34] DOJ's *Title VI Legal Manual* explains that "[m]any Title VI cases involve challenges to site selection decisions, such as the locations selected for construction of highways or facilities that will have negative consequences for the surrounding community. Site selection cases can also involve challenges to the closure or relocation of desirable facilities, such as schools or hospitals."[35] In the clinical research context, deciding to offer a clinical trial in only one location, when multiple potential sites are qualified and available, may, even inadvertently, make it harder for certain racial or ethnic communities to participate.

Title VI's prohibition on disparate impact discrimination, while expansive, is not absolute; courts use a burden-shifting framework to determine whether a recipient of federal funds may justifiably adopt a policy or practice that unintentionally disfavors certain racial or ethnic groups. The government must first make the "prima facie showing" that "the adverse effect of the policy or practice disproportionately affect[s]" members of a particular racial or ethnic group; the funding recipient may then "demonstrate the existence of a substantial legitimate justification for the policy or practice"; and the government may then respond that "the justification … was pretextual" by showing that a less-discriminatory "alternative that would achieve the same legitimate objective" exists.[36] Cases decided prior to *Sandoval* borrowed this burden-shifting framework from Title VII disparate impact cases in the employment context, and at least one case after *Sandoval* applied it to an analogous state law.[37]

This burden-shifting framework is not applied mechanically. For example, courts faced with site selection questions have merged the requirement that funding recipients assert a substantial, legitimate justification with the government's obligation to consider whether less discriminatory alternatives exist.[38] In one case, according to the *Title VI Manual*, although a court said plaintiffs could show that building a new highway on a particular location had a disparate impact on minority communities, the funding recipients provided a substantial, legitimate justification by demonstrating that "the recipients had selected the final freeway location 'so as to minimize impacts upon minority neighborhoods' …. "[39] By this logic, sponsoring institutions would need to demonstrate that they purposely considered access to the opportunity to participate in clinical trials when evaluating the feasibility of potential study sites.

NIH has taken civil rights obligations seriously, releasing guidance in 2015 that explains obligations to "provide equal access to the opportunity to participate in NIH supported research, programs, conferences and other activities."[40] However, in that same document, NIH articulates substantial researcher discretion in administering clinical trials that may, if very broadly construed, come into conflict with Title VI requirements. In particular, NIH stated that "[r]esearch projects are often limited in scope for many reasons, such as the principal investigator's scientific interest, funding limitations, recruitment requirements and other non-discriminatory considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health of the subjects, the scientific study design, or the purpose of the research. It is not anticipated that civil rights protections should alter the fundamental manner in which research projects are designed, conducted, or funded."[41] While several of the reasons NIH articulates — such as the health of the subject — offer clear "substantial legitimate justifications," others — such as the investigator's scientific interest — could, if interpreted broadly, easily perpetuate existing biases or, at worst, serve as mere pretext for discrimination. For example, if researchers elect to focus research on predominately English-speaking

The Journal of Law, Medicine & Ethics, 50 (2022): 101-108. © 2022 The Author(s)

populations so as to avoid translation costs, other communities would effectively lose equal access to the opportunity to participate in clinical trials.[42]

Many in the research and enforcement communities may not fully appreciate that Title VI, correctly construed, mandates that qualified individuals receive equal access to participate in clinical research, even if participation cannot be said to render the possibility of direct clinical benefit. A significant reason so little attention has been paid to the impact of Title VI on clinical research is likely the lack of enforcement. As of June 2021, of the more than 50 recent civil rights resolution agreements and compliance reviews that OCR listed on its website, none of the summaries explicitly cited violations by those engaged in clinical research, though several academic medical centers were among the institutions subject to resolution agreements and compliance reviews.[43] Further, of the "Enforcement Success Stories" listed on OCR's website for complaints related to individuals with limited English proficiency, none of the twenty-five referred to researchers or NIH grant awardees.[44] While OCR has opined on equal access to clinical research on the basis of gender and disability in the context of Section 1557 enforcement, its guidance does not speak to discrimination on the basis of race.[45] The *Sandoval* prohibition on private disparate impact enforcement makes the lack of public enforcement all the more notable.

It is worth noting here that the vast majority of researchers do not intentionally discriminate based on race, color, or national origin. Rather, it is the accumulation of subtle, often unconscious, biases or multiple barriers to research participation that may have significant effects.[46] Further, we recognize that disparate impact cases are difficult to prove, especially where study protocols and inclusion criteria differ substantially across studies. The next section provides our recommendations for the type of institutional enforcement that may prove effective in this context.

Recommendations to Support Enforcement

Improved awareness of and compliance with Title VI would both increase equity in access to clinical trials and improve the representativeness of data collected. NIH and HHS OCR each have the authority to promote compliance with Title VI, by making clear to regulated parties how Title VI applies to the clinical research context.

It is within NIH's power and remit to provide updated guidance that makes clear to researchers and research institutions their obligations under Title VI. The *NIH Grants Policy Statement*, which outlines the obligations of NIH research grant awardees, provides detailed guidance on policies such as animal welfare requirements and ClinicalTrials.Gov registration; however, it provides only two sentences regarding the entire Civil Rights Act of 1964, with limited additional information on individuals with limited English proficiency.[47] While animal welfare protection and clinical trial reporting are fundamental to an ethical research enterprise, Title VI protections against racial and ethnic discrimination would appear, at the very least, equally important. NIH could, for example, borrow from the FDA's 2020 guidance on "Enhancing the Diversity of Clinical Trial Populations," which warns against using "eligibility criteria [that] have become commonly accepted over time ... as a template" and explains that eligibility criteria should ensure "a representative sample of the population for whom the drug has been developed .... "[48] As discussed above, NIH has, to date, provided researchers with substantial flexibility in adopting study designs that may result in disparate treatment of study participants. Yet based on overarching concerns of equity in the allocation of clinical research services, NIH, as a primary and influential federal funder of clinical trials, should provide clear instruction to and guidelines for researchers on disparate impact discrimination against clinical trial participants, outlining steps researchers should take to comply with Title VI. For example, if normal laboratory values differ by race and ethnicity,[49] researchers that establish uniform trial exclusion criteria may unintentionally create a disparate impact on more heavily-excluded minority communities. NIH guidance encouraging researcher awareness of such concerns could help address disparate impact discrimination.

HHS OCR could take a more active role in enforcing Title VI in the clinical research context, and, given the increased attention that COVID-19 has brought to health disparities, one should expect that such enforcement may be forthcoming. There appear to be no reported examples of Title VI enforcement directly in the clinical research context. While researchers and research sponsors can gain substantial scientific and moral value from adopting inclusive study designs,[50] the reality of NIH-funded research in the modern era is that universities and academic medical centers focus their often under-funded research support and compliance efforts on government enforcement priorities. The specter of real enforcement would provide a justification for healthcare organizations to direct resources to track — and to then create programs to address — disparities in access to clinical research. In trying to understand where enforcement in this area might begin, one may consider, by way of example, a

The Journal of Law, Medicine & Ethics, 50 (2022): 101-108. © 2022 The Author(s)

phase 3 study with an eligibility criterion that includes English language requirements.

More comprehensive data collection here can give evidence of possible unintentional but real discriminatory results in clinical research. So that enforcement and guidance efforts can be well calibrated and targeted toward the most serious cases, HHS OCR could require that entities to which Title VI applies collect racial, ethnic, and other demographic data for all clinical trials and report those results to HHS OCR. According to the DOJ's *Title VI Manual*, "Title VI regulations provide agencies with a clear mandate to collect the data necessary to ensure compliance with their Title VI disparate impact regulations."[51] Indeed, HHS already reserves such data collection authorities, and it mandates reporting by NIH grant applicants.[52] While neither Title VI nor HHS's current regulations obligate HHS to engage in data collection for monitoring purposes,[53] the *Title VI Manual* and at least one court case strongly suggest that HHS has the authority to do so.[54] In organizing its data collection, HHS OCR might borrow data reporting guidance from the FDA, which already requires sub-reporting by race and gender, and attempt to leverage existing data sources.[55] Having data on clinical trial participation would allow HHS OCR meaningfully and effectively to enforce Title VI in the clinical trial context, while giving institutions a better sense of their blind spots in this regard.

However, data collection cannot and should not replace community members and researchers who might spontaneously raise questions with IRBs or administrators about unequal access. Recognizing such concerns and elevating them through the institutional compliance process will be important in the ethical conduct of research, as well as in Title VI compliance.

In our view, HHS OCR should provide enforcement guidance, prophylactic instructions, and clear case examples so that the regulated community is enabled to meet its legal obligations. HHS has, in analogous circumstances, pursued enforcement in particularly egregious cases, an approach that research institutions might expect HHS OCR to pursue here. However, engagement with the research community will be essential, since implementation will present numerous challenges. As just one example, if a researcher employed by a health care system generally only provides patient care at one clinical site, it is unclear whether the system would need to require the clinician (or a collaborator employed by the health care system) to enroll across or recruit at other sites serving different patient populations.

HHS OCR should provide enforcement guidance, prophylactic instructions, and clear case examples so that the regulated community is enabled to meet its legal obligations. HHS has, in analogous circumstances, pursued enforcement in particularly egregious cases, an approach that research institutions might expect HHS OCR to pursue here. However, engagement with the research community will be essential, since implementation will present numerous challenges.

Conclusion

Title VI of the Civil Rights Act prohibits all programs or activities of universities and medical centers receiving Federal financial assistance from discriminating on the basis of race, color, or national origin. HHS has, through regulation, extended this prohibition to include policies creating a disparate impact, even if the discrimination is not intentional. Furthermore, Title VI prohibits discrimination in both the benefits of and participation in such programs and activities. Thus, Title VI requires that clinical researchers at universities, academic medical centers, hospitals, and community health centers take affirmative steps to ensure that all individuals have an equal opportunity to participate in clinical research.

However, following *Sandoval*, government enforcement is essential to ensuring that potential research participants receive the benefit of these protections. To date, NIH has offered only ambiguous guidance that fails to explain what inclusive clinical trial participation requires; and HHS OCR has not taken action to enforce Title VI protections in the clinical research context. Both agencies should communicate the intention and effect of Title VI to the research community more clearly, explaining, for example, what considerations should enter research site selection

The Journal of Law, Medicine & Ethics, 50 (2022): 101-108. © 2022 The Author(s)

https://doi.org/10.1017/jme.2022.14 Published online by Cambridge University Press

decisions, among others. As with any regulatory and enforcement regime, the informed participation of the regulated community will be essential to a successful outcome. In fact, researchers have already begun carefully to explore issues related to bias in research,[56] and we urge government officials to review that literature in crafting policies.

Ultimately, government enforcement of anti-discrimination protections in clear and egregious cases should be anticipated, and, if undertaken prudently, could promote awareness and compliance in the larger research community. More representative trials will yield better, more representative research results, make more opportunities available to underrepresented and historically marginalized communities, and nudge research institutions to think critically about previously unrecognized impacts of their study design and conduct decisions. These steps offer promise of improving the lives of participants and the quality, impact, and trustworthiness of clinical research.

Note

Mr. Liss reports that, at the time he worked on this article, he worked for a large international law firm, which represents many clients that would be affected by these legal issues. Mr. Peloquin and Mr. Barnes work for Ropes & Gray LLP.

References

1. S.B. Thomas and S. Crouse Quinn, "The Tuskegee Syphilis Study, 1932 to 1972: Implications for HIV Education and AIDS Risk Education Programs in the Black Community," *American Journal of Public Health* 81, no. 11 (1991): 1498-1505, *available at* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1405662/> (last visited December 6, 2021).
2. L.E. Flores et al., "Assessment of the Inclusion of Racial/Ethnic Minority, Female, and Older Individuals in Vaccine Clinical Trials," *JAMA Network Open* 4, no. 2 (2021): 1-11.
3. "Drug Trials Snapshots," Food and Drug Administration, 2020, *available at* <https://www.fda.gov/media/145718/download> (last visited December 6, 2021).
4. *21st Century Cures Act*, Sec. 2053, 42 U.S.C. § 289a–2(c)(2); Food and Drug Administration, *Collection of Race and Ethnicity Data in Clinical Trials*, FDA-2016-D-3561 (2016), *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials> (last visited December 6, 2021).
5. US HHS, National Institutes of Health, "Rapid Acceleration of Diagnostics (RADx)," RADx Programs, *available at* <https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs#radx-up> (last visited December 6, 2021).
6. Food and Drug Administration, "Enhance EQUITY Initiative," *available at* <https://www.fda.gov/consumers/minority-health-and-health-equity/enhance-equity-initiative> (last visited.
7. 42 U.S.C. § 2000d (2018); *Alexander v. Sandoval*, 532 U.S. 275, 280 (2001).
8. *Price Waterhouse v. Hopkins*, 490 U.S. 228, 271 (1989) (O'Connor, J., concurring).
9. 42 U.S.C. § 2000d-1 (2018).
10. 45 C.F.R. § 80.3(b)(2) (2019).
11. U.S. Department of Justice and Department of Health & Human Services Office of Civil Rights, *Title VI Child Welfare Guidance*, (Washington, DC: December 2019), *available at* <https://www.justice.gov/crt/title-vi-child-welfare-guidance> (last visited December 6, 2021).
12. *Lau v. Nichols*, 414 U.S. 563 (1974).
13. *Alexander v. Sandoval*, 532 U.S. 275, 293 (2001).
14. A. Kimmel, R. Epstein, and J. Ferraro, "The Sandoval Decision and Its Implications for Future Civil Rights Enforcement," *Florida Bar Journal* 76, no. 1 (2002): 24, *available at* <https://www.floridabar.org/the-florida-bar-journal/the-sandoval-decision-and-its-implications-for-future-civil-rights-enforcement/> (last visited December 6, 2021).
15. 42 U.S.C. § 2000d (2018).
16. *Grove City College v. Bell*, 465 U.S. 555, 572 (1984).
17. *Civil Rights Restoration Act of 1987*, Sec. 2, Pub. L. No. 100-259, 102 Stat. 28, 28 (1988).
18. 42 U.S.C. § 2000d–4a (2018).
19. 45 C.F.R. § 80.13(g) (2019).
20. 42 U.S.C. § 2000d–1.
21. Department of Health and Human Services Office of Civil Rights, "What Qualifies as 'Federal Financial Assistance' for Purposes of Civil Rights Complaints Handled by OCR?", 2015, *available at* <https://www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-federal-financial-assistance/301/index.html> (last visited December 6, 2021); Office of Extramural Research, *NIH Grants Policy Statement,* "Definition of Terms," at Sec. 1.2, National Institutes of Health, 2021, *available at* <https://grants.nih.gov/grants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm> (last visited December 6, 2021).
22. Amending the Regulations Governing Nondiscrimination on the Basis of Race, Color, National Origin, Handicap, Sex, and Age To Conform to the Civil Rights Restoration Act of 1987, 70 *Fed. Reg.* 24,314, 24,315.
23. 70 *Fed. Reg.* at 24,316.
24. 45 CFR § 92.2(a)(1) (2019); Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 *Fed. Reg.* 37160, 37171 (June 19, 2020).
25. 45 C.F.R. § 80.4(a)(1) (2019).
26. Office of Extramural Research, *NIH Grants Policy Statement*, Secs. 4.1.2, 4.1.2.1, 4.1.2.5.
27. Department of Health and Human Services, *Assurance of Compliance*, Form 690, 2019, *available at* <https://www.hhs.gov/sites/default/files/form-hhs690.pdf> (last visited December 6, 2021).
28. Office of Extramural Research, "Civil Rights Protections," *NIH Grants Policy Statement*, at Secs. 4.1.2, 4.1.2.1, 4.1.2.5.
29. Department of Health and Human Services, *Assurance of Compliance.*
30. *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802 (1973).
31. *Civil Rights Act of 1964*, 42 U.S.C. § 2000d; 45 CFR § 80.3.
32. *United States v. McDonnell*, 136 S. Ct. 2355, 2369 (2016) (quoting *Arlington Central School Dist. Bd. of Ed. v. Murphy*, 548 U.S. 291, 299, n. 1 (2006)); *Bailey v. United States*, 516 U.S. 137, 146 (1995).
33. E.J. Leib and J.J. Brudney, "The Belt-and-Suspenders Canon," *Iowa Law Review* 105, no. 2 (2020): 737.
34. Resolution agreement between the U.S. Department of Health and Human Services Office for Civil Rights and the University of Pittsburgh Medical Center, transaction number: 10-106043, Office for Civil Rights, August 2010, *available at* <https://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/upmcra.pdf> (last visited December 6, 2021).
35. Civil Rights Division, "Proving Discrimination — Disparate Impact," in *Title VI Legal Manual.*
36. Civil Rights Division, "Proving Discrimination — Disparate Impact," in *Title VI Legal Manual*, Department of Justice, 2021, *available at* <https://www.justice.gov/crt/fcs/T6Manual7> (last visited December 6, 2021).
37. *Darensburg v. Metro. Transp. Comm'n*, 636 F.3d 511, 519 (9th Cir. 2011) (turning to Title VII disparate impact analysis to analyze a claim similar to Title VI arising under California law); *New York Urban League v. New York*, 71 F.3d 1031, 1036 (2d Cir. 1995) (applying the burden-shifting framework pre-

The Journal of Law, Medicine & Ethics, 50 (2022): 101-108. © 2022 The Author(s)

Sandoval Title VI case); *Georgia State Conference of Branches of NAACP v. Georgia*, 775 F.2d 1403, 1417 (11th Cir. 1985) (same).
38. Civil Rights Division, "Proving Discrimination — Disparate Impact," in *Title VI Legal Manual*.
39. Civil Rights Division, "Proving Discrimination — Disparate Impact," in *Title VI Legal Manual*; *Coalition of Concerned Citizens Against I-670 v. Damian*, 608 F. Supp. 110, 127 (S.D. Ohio 1984).
40. National Institutes of Health, *Civil Rights Protections in NIH-Supported Research, Programs, Conferences and Other Activities*, NOT-OD-15-152, September 2015, *available at* <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-152.html> (last visited December 6, 2021).
41. National Institutes of Health, *"Civil Rights Protections in NIH-Supported Research, Programs, Conferences and Other Activities*.
42. A.V. Muthukumar, W. Morrell, and B. E. Bierer, "Evaluating the Frequency of English Language Requirements in Clinical Trial Eligibility Criteria: A Systematic Analysis Using ClinicalTrials.gov," *PLoS Medicine* 18, no. 9 (2021): e1003758, *available at* <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003758> (last visited December 6, 2021).
43. "Recent Civil Rights Resolution Agreements & Compliance Reviews," Office of Civil Rights, Department of Health and Human Services, *available at* <https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/index.html> (last visited December 6, 2021).
44. "Enforcement Success Stories Involving Persons with Limited English Proficiency," Office of Civil Rights, Department of Health and Human Services, *available at* <https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/limited-english-proficiency/index.html> (last visited December 6, 2021).
45. "Section 1557: Frequently Asked Questions," Office of Civil Rights, Department of Health and Human Services, *available at* <https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html> (last visited December 6, 2021).
46. A. Byrne and A. Tanesini, "Instilling New Habits: Addressing Implicit Bias in Healthcare Professionals," *Advances in Health Sciences Education* 20 (2015): 1255-1262; C. FitzGerald and S. Hurst, "Implicit Bias in Healthcare Professionals: A Systematic Review," *BMC Medical Ethics* 18, no. 19 (2017); L. Skopec, D. Gonzalez, and G. M. Kenney, "Most Adults Who Feel Treated or Judged Unfairly by Health Care Providers Report Adverse Consequences," Urban Institute, August 2021, *available at* <https://www.urban.org/research/publication/most-adults-who-feel-treated-or-judged-unfairly-health-care-providers-report-adverse-consequences> (last visited December 6, 2021).
47. Office of Extramural Research, "Civil Rights Protections" in *NIH Grants Policy Statement*, at Sec. 4.1.2; Office of Extramural Research, *NIH Grants Policy Statement*, at Secs 1.2, 4.1.1, 4.1.3.
48. Food and Drug Administration, *Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry*, November 2020, *available at* <https://www.fda.gov/media/127712/download> (last visited December 6, 2021).
49. L.E. Merz and M. Achebe, "When Non-Whiteness Becomes a Condition," *Blood* 137, no. (2021): 13-15.
50. B. Bierer, S. White, L.Meloney, H. Ahmed, D. Strauss, and L. Clark, *Achieving Diversity, Inclusion, and Equity in Clinical Research*, Multi-Regional Clinical Trials Center, 2021, *available at* <https://mrctcenter.org/diversity-in-clinical-research/guidance/guidance-document/> (last visited December 6, 2021).
51. Civil Rights Division, "Proving Discrimination — Disparate Impact," in *Title VI Legal Manual*, Department of Justice, 2021, *available at* <https://www.justice.gov/crt/fcs/T6Manual7#Z> (last visited December 6, 2021).
52. 45 C.F.R. § 80.6(b); *accord* 28 C.F.R. § 42.406(a); National Institutes of Health, *NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research*, NOT-OD-01-053, 2001, *available at* <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html> (last visited December 6, 2021).
53. *Madison-Hughes v. Shalala*, 80 F.3d 1121, 1125 (6th Cir. 1996).
54. Civil Rights Division, "Proving Discrimination — Disparate Impact," in *Title VI Legal Manual*, Department of Justice, 2021, *available at* <https://www.justice.gov/crt/fcs/T6Manual7#Z> (last visited December 6, 2021); *Gillis v. U.S. Dept. of H. H. Services*, 759 F.2d 565, 576 (6th Cir. 1985) (finding that monitoring efforts of assurances that recipients provide under the Hill-Burton statute "fall squarely within the agency's exercise of discretion").
55. Food and Drug Administration, *Collection of Race and Ethnicity Data in Clinical Trials*, FDA-2016-D-3561, 2016, *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials> (last visited December 6, 2021).
56. Bierer et al., *supra* note 50.

The Journal of Law, Medicine & Ethics, 50 (2022): 101-108. © 2022 The Author(s)