

# **BANKS – Funding Race Science**

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## **Funding Race as Biology: The Relevance of “Race” in Medical Research**

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### **Abstract**

Most scientists agree that race and ethnicity (ethno-race) classifications are the result of social and political conditions, as opposed to biological differences. But there is disagreement about the scientific validity of these categories. A number of scientists use ethno-race as a surrogate for various socioeconomic and environmental factors. Using race as a *biological* category can reflect and reinforce racial stratification as well as racist notions of inherent human difference. Questions surrounding the appropriateness of ethno-race classifications in medical research have been heightened by two decades of federal legislation that contains initiatives on minority health.

This article proceeds from the assumption that conventional legal challenges to the inappropriate use of ethno-race in federally funded biomedical research are fraught with problems. Further, it argues that the current regulatory approach used by high impact medical journals and the federal government to discourage misuse of ethno-race comes too late. A more effective approach is stringent review and clearer standards about the use of ethno-race in biomedical research at the grant proposal stage.

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## Introduction: *‘dem Bones, ‘dem Bones, ‘dem “black” Bones*

In 1940 the State of North Carolina classified a friend as “colored” despite her “white skin, blue eyes, [and] curling blond hair.”<sup>1</sup> She—like her parents, grand-parents, and many other black Americans—is often mistaken for white.<sup>2</sup> Sixty years later when she went for a bone densitometry test—a must for post menopausal women—the technician asked her to fill out a form that asked her race. Surprised, she asked why. The technician replied: “since the bones of black people are different than the bones of white people, the doctor needs this

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<sup>1</sup> Judy Scales-Trent, Bones Essay (Nov. 7, 2008) (unpublished copy on file with author). In 1940 under the North Carolina State Constitution and the state anti-miscegenation statute a “Negro” or colored person was someone “of Negro descent to the third generation, inclusive,” in other words, a “person who has one-eighth [or more] Negro blood in his veins.” State v. Miller, 29 S.E.2d 751, 752 (N.C. 1944) (citing N.C. CONST. art. XIV, § 8; N.C. GEN. STAT. § 51-3).

<sup>2</sup> See generally JUDY SCALES-TRENT, NOTES OF A WHITE BLACK WOMAN: RACE, COLOR, COMMUNITY (1995); GREGORY HOWARD WILLIAMS, LIFE ON THE COLOR LINE: THE TRUE STORY OF A WHITE BOY WHO DISCOVERED HE WAS BLACK (1996).

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information to interpret the scan correctly.”<sup>3</sup>

The radiologist who analyzed my friend’s bone scan acknowledged that there is a debate within the radiology community about the scientific validity of interpreting an x-ray through the lens of race.<sup>4</sup> But he claimed it is impossible to interpret the bone scan without factoring in race because the machines which analyze the bone scan can only produce an analysis if the race of the person being analyzed is included. The doctor could not explain how the x-ray machine defined “race” replying that the definitions “were created by the companies that built the machines.”<sup>5</sup>

My friend asked if there was any way she could get more helpful advice about the condition of her bones. The doctor thought for a moment, then suggested that perhaps my friend should have her bone densitometry test performed twice, once as “white”, then as “black”, and the condition of her bones would lie somewhere between the two results. She writes: “But one-half of a fantasy definition of ‘white’ plus one-half of a fantasy definition of ‘black’ will only yield one whole fantasy; it will not provide a sound medical diagnosis.”<sup>6</sup> Thus she marked “black” or “African American” because that had always been her legal and social identity. So what did the results really tell her doctor?

For years she taught and wrote about the social construction of race and knew that her doctor’s explanation about the use of race as a biological term by the radiology community was flawed. It was reminiscent of the World War II era when the Nazis kept “separate blood banks for ‘Jewish blood’ and ‘Aryan blood,’ [and] American blood banks were separating ‘white blood’ and ‘black blood’”<sup>7</sup> There is a long and continuing history of “unconscionable medical research” involving black Americans.<sup>8</sup>

In 1950 the United Nations Educational Scientific & Cultural Organization (UNESCO), mindful of race science’s dark and not so distant history<sup>9</sup>, drafted a statement on the use of race in modern

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<sup>3</sup> Scales-Trent, *Bones Essay*, *supra* note 1.

<sup>4</sup> For a discussion of this debate, see Anne Fausto-Sterling, *Bare Bones of Race*, 38 SOC. STUD. SCI. 657, 659 (2008).

<sup>5</sup> *Bones Essay*, *supra* note 1, at 2.

<sup>6</sup> *Bones Essay*, *supra* note 1, at 3.

<sup>7</sup> *Bones Essay*, *supra* note 1, at 2.

<sup>8</sup> HARRIET A. WASHINGTON, *MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT* 2 (2006).

<sup>9</sup> For a discussion of historical misuse of race in science, see *id.*; Raj Bhopal, *Is Research*

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science.<sup>10</sup> This statement, developed by an esteemed group of anthropologists, psychologists and sociologists, concludes: “[f]or all practical purposes ‘race’ is not so much a biological phenomenon as a [damaging] social myth.”<sup>11</sup> Today most scientists agree that race and ethnicity (ethno-race) classifications are the result of social and political conditions, as opposed to biological differences. But there is disagreement about the scientific validity of these categories.<sup>12</sup>

Even though an increasing number of scientists believe that too often ethno-race is used as a surrogate for various socioeconomic and environmental factors,<sup>13</sup> for most of the late twentieth century, social science and medical researchers continued to use ethno-race in a biological context. Nevertheless, there are times when ethno-racial designations have value in medical research. As one scholar writes “using race as a *social category*” to study the impact of racism on health and on access to medical care is critical to eliminating health inequities

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*into Ethnicity and Health Racist, Unsound, or Important Science?*, 314 BRIT. MED. J. 1751 (1997); Lundy Braun et al., *Racial Categories in Medical Practice: How Useful Are They?*, 4 PLOS MED. 1423 (2007); Charis Thompson, *Race Science*, THEORY, CULTURE & SOC’Y, May 2006, at 547.

<sup>10</sup> UNESCO acted in response to “a resolution adopted by the UN Economic and Social Council asking UNESCO . . . ‘to consider the desirability of initiating and recommending the general adoption of a programme of disseminating scientific facts designed to remove what is generally known as racial prejudice.’” UNESCO, *THE RACE QUESTION IN MODERN SCIENCE: THE RACE CONCEPT RESULT OF AN INQUIRY 5* (1952), available at <http://unesdoc.unesco.org/images/0007/000733/073351eo.pdf>.

<sup>11</sup> *Id.* at 101. A half of century later, the Human Genome Project seemed to confirm the scientific irrelevance of race finding “high levels of genetic similarity within human species.” Dorothy E. Roberts, *Legal Constraints on the Use of Race in Biomedical Research: Toward a Social Justice Framework*, 34 J.L. MED. & ETHICS 526, 526 (2006). For a discussion of the Human Genome Project, see Nat’l Human Genome Research Inst., *All About the Human Genome Project*, <http://www.genome.gov/10001772> (last visited Dec. 7, 2010). As a result, some scholars speculated that genetic differences “would replace race as the preeminent means of grouping people for scientific purposes.” Roberts, *supra*, at 526. But genetic differences did not replace racial categories, instead, debates about the scientific validity of race reemerged in connection with genomic, biomedical and biotechnology research. *Id.*

<sup>12</sup> See generally JENNY REARDON, *RACE TO THE FINISH: IDENTITY AND GOVERNANCE IN AN AGE OF GENOMICS* (2005); Shomarka O.Y. Keita & Rick A. Kittles, *The Persistence of Racial Thinking and the Myth of Racial Divergence*, 99 AM. ANTHROPOLOGIST 534 (1997). Because self-identified ethno-race often serves as a “poor proxy for underlying genetic relatedness” many researchers have begun using DNA estimates of ancestry (ancestral DNA) in genetic-association research. Timothy Caulfield et al., *Race and Ancestry in Biomedical Research: Exploring the Challenges*, 1 GENOME MED. art. no. 8, at 8.1, 8.2 (2009). The major genetic variations, however, correspond to the major continents, giving rise to the same racial distinctions the use of ancestry seeks to avoid. *Id.* at 8.2.

<sup>13</sup> Otis W. Brawley & Harold P. Freeman, Editorial, *Race and Outcomes: Is This the End of the Beginning for Minority Health Research?*, 91 J. NAT’L CANCER INST. 1908 (1999).

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based on race.<sup>14</sup> But she cautions that using race as a *biological* category can reflect and reinforce racial stratification as well as racist notions of inherent human difference.<sup>15</sup> Several commentators call this phenomenon the reification of race, where the social concept of race is transformed “into a specific, definite, concrete, and now presumably genetic category which can feed back into preexisting lay understandings of racial difference.”<sup>16</sup>

Congress regulates a great deal of medical research with the promise of federal monies. The relevance of ethno-race in medical research has been heightened by two decades of federal legislation, most notably the U.S. National Institutes of Health Revitalization Act of 1993 [hereinafter the Revitalization Act], which contains initiatives on minority health.<sup>17</sup> The Revitalization Act, among other things, requires that women and “minority groups” be included in all intramural and extramural National Institutes of Health (NIH)-funded biomedical and behavioral research.<sup>18</sup> Since most biomedical research is funding driven, minority health initiatives, by promoting greater racial diversity among clinical subjects, generate a medical research market that may also unintentionally promote the misuse of ethno-race.

A few legal commentators express concern about the resulting re-emergence of race in biomedical studies, but most concede that legal challenges to the current medical research practices may not be the most effective means of quickly minimizing or remedying the problem.<sup>19</sup> Litigation may actually discourage needed and valid race-related studies.<sup>20</sup> Courts searching for ethno-racial medical biases may become overzealous and act in ways that actually thwart positive race-related

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<sup>14</sup> Roberts, *supra* note 11, at 527.

<sup>15</sup> *Id.*

<sup>16</sup> OSAGIE K. OBASOGIE, CENTER FOR GENETICS & SOC’Y, “PLAYING THE GENE CARD”: A REPORT ON RACE AND HUMAN BIOTECHNOLOGY 5 (2009), available at [http://geneticsandsociety.org/downloads/complete\\_PTGC.pdf](http://geneticsandsociety.org/downloads/complete_PTGC.pdf). Jonathan Kahn argues that the approval of BiDil signals that “powerful federal agencies have legitimized the use of race as a marker for biological difference.” Jonathan Kahn, *How a Drug Becomes “Ethnic”*: Law, Commerce, and the Production of Racial Categories in Medicine, 4 YALE J. HEALTH POL’Y & ETHICS 1, 6 (2004). Anthropologist Alan Goodman characterizes this type of research as “a comeback in racialized notions of biology.” *Id.*

<sup>17</sup> Roberts, *supra* note 11, at 527.

<sup>18</sup> Karen H. Rothenberg, *Gender Matters: Implications for Clinical Research and Women’s Health Care*, 32 HOUS. L. REV. 1201, 1231-32 (1996).

<sup>19</sup> For a discussion of this point, see Osagie K. Obasogie, *Beyond Best Practices: Strict Scrutiny as a Regulatory Model for Race-Specific Medicines*, 36 J.L. MED. & ETHICS 491, 494-95 (2008).

<sup>20</sup> *Id.* at 495; Erik Lillquist & Charles A. Sullivan, *The Law and Genetics of Racial Profiling in Medicine*, 39 HARV. C.R.-C.L. L. REV. 391, 466 (2004).

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medical research, such as inquiries into access to care and equal treatment.<sup>21</sup> Nevertheless, federally funded biomedical research that uses race inappropriately is socially harmful because, as I will discuss throughout this article, the practice tends to perpetuate the disputed notion that race is biological, and evokes the historical baggage associated with race science. Thus some government regulation or oversight is warranted where public funds are involved.

Only a handful of legal scholars have addressed the dangers inherent in the uncritical use of ethno-race in medical studies and the debates within the biomedical research community about the use of ethno-race in research.<sup>22</sup> None, I contend, provide a comprehensive overview of the issue nor propose an effective remedy. While there is a general consensus that race and other social classifications influence health, “there is little agreement about why or how [ethno-]race matters, how best to study its effects, and how to translate and communicate research results from racially stratified studies.”<sup>23</sup>

Legal scholar Dorothy Roberts posits that “[f]ederal funding agencies’ control over the funding for biomedical research is a powerful basis for restricting the use of race” in medical studies.<sup>24</sup> She offers a few general suggestions for how funding restrictions might operate.<sup>25</sup> In this article I build on Roberts’s initial suggestions by offering more

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<sup>21</sup> Lillquist & Sullivan, *supra* note 20, at 466.

<sup>22</sup> One proposes what she calls a “social justice framework” designed to encourage the appropriate use of race in medical research. Roberts, *supra* note 11, at 527. Others explore the constitutionality of using race in scientific research. Lillquist & Sullivan, *supra* note 20, at 391. Still other scholars focus on narrower issues like the regulatory role of the Food and Drug Administration (FDA) in determining whether to approve race-specific medicine. Osagie K. Obasogie, *Beyond Best Practices: Strict Scrutiny as a Regulatory Model for Race-Specific Medicines*, 36 J.L. MED. & ETHICS 491 (2008) (arguing that the FDA should use the constitutional law idea of strict scrutiny in the classification of race to decide when racial categories are acceptable in biomedicine); Kahn, *supra* note 16 (arguing for tighter FDA regulation of race specific drugs). Finally, there are a few scholars who argue that race may be relevant in some but not all medical studies. See, e.g., Michael D. Ruel, *Using Race in Clinical Research to Develop Tailored Medications: Is the FDA Encouraging Discrimination or Eliminating Traditional Disparities in Health Care for African Americans?*, 27 J. LEGAL MED. 225 (2006) (arguing while using race in medical trials is acceptable, the government needs to develop rules on this based on scientific evidence to make sure discrimination does not occur).

<sup>23</sup> Caulfield et al., *supra* note 12, at 8.2. The authors conclude: “[r]esearch that simultaneously assesses both genetic and environmental contributions to disease risk, drug response and other health-related variation, and that deliberately puts such findings in the context of self-identified race is urgently needed,” or else race will continue to be used, problematically, in biomedical research. *Id.* at 8.2.

<sup>24</sup> Roberts, *supra* note 11, at 529.

<sup>25</sup> *Id.* at 530-33.

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specific recommendations for federal funding restrictions on biomedical research that uses ethno-racial categories.

This article proceeds from the assumption that there are few clear instances, other than perhaps access to health care or measuring equality in medical treatment, where the use of ethno-race in medical research is appropriate. Even in those limited situations, the justification for using ethno-race, how the ethno-racial categories are defined, and the method for assigning ethno-race warrant close scrutiny and oversight, especially when these studies are funded with federal money. In the next section I explain the scientific basis for my assumption. First I explore the debates within the medical community about the connection between race and biology in biomedicine. Next I examine literature on race-related stress to determine whether this might be an instance where ethno-racial labels help explain health outcomes, concluding that guidelines or regulation are needed.

The third section of this article examines two sets of guidelines on the use of ethno-race in biomedical research: guidelines adopted by high impact medical journals and federal guidelines on the use of ethno-race in federal funded biomedical research. Finding these measures inadequate, I conclude that the only way to quickly change research behavior in this area is through greater regulation and oversight of federal medical research grants. More stringent government regulation and oversight of federally funded biomedical research grants that use ethno-race may trigger changes in the medical culture faster than litigation.

In the fourth section I proposed a regulatory scheme that offers a standard to measure the appropriateness of ethno-race in applications for federally funded biomedical research that will cause both researchers and grant reviewers to give more thought to how and why ethno-race is used in research protocols. I concede that my proposal is a first step, and that meaningful progress also requires strong and effective measures designed to change how biology is taught in undergraduate, graduate, and professional schools. Without a change in the medical culture, another generation of researchers and health care providers will be trained to think about ethno-racial differences inappropriately.

Before effective remedies for the problem described can be discussed, it is important to clarify both the meaning and use of the term “race” in scientific discussions. The next section of this paper looks at debates within the scientific community about the meaning of ethno-racial labels.

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## II. “If Race is the Answer, What is the Question?”<sup>26</sup>: Debates on the Use of Race in Research

### A. Links between Race and Biology

#### 1. Contemporary Debates

In the late nineteenth century “[s]cientists . . . racialized science, naming and ranking ‘races’ based on their assigned biological and social worth,”<sup>27</sup> and much of the resulting research from this era is “racist, unethical, and ineffective.”<sup>28</sup> Even more troubling, race science was used to justify slavery, anti-immigration policies, and imperialism.<sup>29</sup> Although race science was abandoned by the mid-twentieth century, a few researchers in the 1990s expressed concerns that ethno-race still was being misused in contemporary biomedical research.<sup>30</sup> This section looks at the debates within research communities about the use of racial categories in biomedical research.

Most contemporary scientists concede that nineteenth century stereotypes of race and racial variations probably reflect the superficial understanding of the relationship between ethno-race and biological difference/lack of difference held by scientists in that era. The debate continues, however, over whether race has *any* legitimacy as a scientific concept, and more fundamentally, whether and how to study human biological diversity. Biologist Marcus Feldman, and his co-authors write: “[t]he issue of whether race is a biologically useful or even

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<sup>26</sup> Taken from the title of an article about the misuse of “race” to explain persistent health outcome disparities among racial and ethnic groups in the United States. Nancy Krieger, *If Race is the Answer, What is the Question? On “Race”, Racism and Health: A Social Epidemiologist’s Perspective*, IS RACE REAL? (June 7, 2006), <http://raceandgenomics.ssrc.org/Krieger/>.

<sup>27</sup> Bhopal, *supra* note 9, at 1751.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> Trevor A. Sheldon & Hilda Parker, *Race and Ethnicity in Health Research*, 14 J. PUB. HEALTH MED. 104, 104 (1992). The authors write that “[h]ealth research appears to be reflecting the process of ‘racialization’ . . . whereby the idea of race or ethnicity is increasingly being introduced to help define or give meaning to the population [being studied]” and argue for more thought and care in the use of race and ethnicity as health research variables. Their article was part of a debate within the United Kingdom about the use and misuse of race and ethnicity. *See, e.g.*, Jenny L. Donovan, *Ethnicity and Health: A Research Review*, 19 SOC. SCI. MED. 663 (1984) (concluding that the studying particular diseases or illnesses affecting ethnic groups tends to place blame on subalterns rather than attribute these health problems to the economic and social structures of the countries in which they reside); R.S. Bhopal et al., *Inappropriate Use of the Term “Asian”: An Obstacle to Ethnicity and Health Research*, 13 J. PUB. HEALTH MED. 244 (1991).



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meaningful concept when applied to humans in a medical context is controversial.”<sup>31</sup> But the authors claim that there really is “no contradiction” between the bodies of evidence on each side of the debate. This is because the issue conflates two questions: whether DNA sequences between populations are related to “major geographical origin” and whether “most genetic diversity occurs within groups.”<sup>32</sup> The answer to both questions, according to the authors, is yes.<sup>33</sup> Therefore, those who argue that race is relevant present evidence linking race to geographic origin, and those who argue that race is irrelevant present evidence of genetic diversity within racial groups.

This debate does not contest the use of socially constructed ethno-racial categories to measure differences in access to health care, delivery of health care, and equal medical treatment. Studies such as these measure social attitudes of health care providers. Therefore, they are distinguishable from studies that use ethno-race to explain biological differences in disease or medical outcomes unrelated to social disparities in health care. Nevertheless, as my friend’s bone density test experience illustrates, the undifferentiated connection between race and biology persists in America.

### 2. Sickle Cell Disease and Race

Mathematical biologist Marcus Feldman, and his co-authors, in discussing the connection between race and genetics, argue that ancestral geographical origin can be useful in diagnosis and treatment, but a person’s racial classification, whether self-identified or assigned, “is both too broad and too narrow a definition of ancestry to be biologically useful.”<sup>34</sup> They specifically cite sickle-cell disease, widely thought by Americans to be a trait connected to African ancestry, but which in reality is “characteristic of ancient ancestry in a geographic region where malaria was endemic.”<sup>35</sup> Since individuals with the sickle cell trait do

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<sup>31</sup> Marcus W. Feldman et al., *A Genetic Melting-Pot*, 423 NATURE 374 (2003) The authors explain: “Race as a biological concept has had a variety of meanings. In the taxonomic literature, a race is any distinguishable type within a species . . . . In 1937 Theodosius Dobzhansky introduced the idea of geographical races—populations of species that differ in the frequencies of one or more genetic variants . . . .The classic definition of race . . . is based on phenotypes such as skin colour, facial features and hair . . . . An underlying assumption is that all of these defining features . . . are characteristic of the genome in general.” *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* See also Anthony C. Allison, *Two Lessons from the Interface of Genetics and Medicine*, 166 GENETICS SOCIETY AM. 1591, 1592 (2004) (In testing his hypothesis that sickle cell was related to malaria, Allison found that the “distribution involving diverse

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not get malaria, researchers now believe that the trait is a genetic mutation that developed as protective measure in areas around the world where malaria is common.<sup>36</sup>

Malaria once was most common in Africa and around the Mediterranean.<sup>37</sup> Thus the trait also is found in “Portuguese, Spaniards, French Corsicans, Sardinians, [and] Sicilians, mainland Italians, Greeks, Turks and Cypriots.”<sup>38</sup> Today Sickle Cell disease is most common in Middle Eastern countries like Lebanon, Israel, Saudi Arabia, Kuwait and Yemen and Near Eastern countries like India and Sri Lanka.<sup>39</sup>

The tendency in the United States to link sickle cell disease to black Americans stems from the fact that black Americans are more likely than any other ethno-racial group in the country to have the sickle cell trait.<sup>40</sup> A closer examination of the evidence indicates, however, that geography, rather than race, factors into the trait’s prevalence.<sup>41</sup> Most black Americans are descendants of enslaved Africans from West and Central Africa where the disease is most common.<sup>42</sup> It follows therefore

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populations, supported the belief that an environmental factor, malaria transmission, was the principle determinant of high sickle-cell frequencies.”); Jenny L. Donovan, *Ethnicity and Health: A Research Review*, 19 SOC. SCI. MED. 663, 665 (1984) (“Sickle-cell anemia first occurred in Britain when immigrants arrived from Africa and the Caribbean where the disease had developed to give partial immunity to endemic malaria.”).

<sup>36</sup> *Sickle Cell Disease*, U. MD. MED. CTR., <http://www.umm.edu/blood/sickle.htm> (last visited Dec. 16, 2010); Allison, *supra* note 35, at 1592-93.

<sup>37</sup> *Sickle Cell Disease*, *supra* note 36.

<sup>38</sup> *Who Is Affected?*, SICKLE CELL DISEASE ASS’N OF AMERICA, INC., [http://www.sicklecelldisease.org/about\\_scd/affected1.phtml](http://www.sicklecelldisease.org/about_scd/affected1.phtml) (last visited Dec. 16, 2010). According to the National Heart Lung and Blood Institute, sickle cell anemia is “most common in people whose families come from Africa, South or Central America (especially Panama), Caribbean islands, Mediterranean countries (such as Turkey, Greece, and Italy), India, and Saudi Arabia.” See *Who Is at Risk for Sickle Cell Anemia?*, NAT’L HEART LUNG AND BLOOD INST., [http://www.nhlbi.nih.gov/health/dci/Diseases/Sca/SCA\\_WhoIsAtRisk.html](http://www.nhlbi.nih.gov/health/dci/Diseases/Sca/SCA_WhoIsAtRisk.html) (last visited Dec. 7, 2010).

<sup>39</sup> *Who Is Affected?*, *supra* note 38.

<sup>40</sup> Eight percent of African Americans have the sickle cell trait. DIV. OF BLOOD DISEASES AND RESOURCES, NAT’L INST. OF HEALTH, *THE MANAGEMENT OF SICKLE CELL DISEASE 15* (4th ed. 2002), available at

[http://www.nhlbi.nih.gov/health/prof/blood/sickle/sc\\_mngt.pdf](http://www.nhlbi.nih.gov/health/prof/blood/sickle/sc_mngt.pdf); *Learning About Sickle Cell Disease*, NAT’L HUMAN GENOME RESEARCH INSTITUTE, available at <http://www.genome.gov/page.cfm?pageID=10001219> (last visited Dec. 16, 2010) (“In the United States, sickle cell disease is most prevalent among African Americans. About one in 12 African Americans and about one in 100 Hispanic Americans carry the sickle cell trait . . .”).

<sup>41</sup> See generally Allison, *supra* note 35.

<sup>42</sup> *Who Is Affected?*, *supra* note 38. According to the University of Maryland Medical Center, “[s]ickle cell disease primarily affects those of African descent and Hispanics of Caribbean ancestry, but the trait has been found in those with Middle Eastern, Indian,

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that, in the United States, African ancestry is a factor in the prevalence of sickle cell among black Americans. Although most states routinely test all newborns for the trait,<sup>43</sup> public health officials may continue to link sickle cell to black Americans and target this population for outreach.<sup>44</sup> This results from an incorrect assumption that the prevalence of sickle cell among black Americans is due to a connection between biology and race.<sup>45</sup>

As Feldman and his co-authors caution, other variables like migration and mating may result in “new populations, thus, ‘[a] person classified as ‘black’ or ‘Hispanic’ by social convention could have any mixture of ancestries, as defined by continent of origin.”<sup>46</sup> Physicians might fail to test individuals for sickle cell disease because they are not classified as black. If the disease remains undiagnosed and untreated, severe medical consequences, or even death, may result. Thus it may be more important to know a patient’s family medical history than race, since a person who identifies as black, or white, may have grandparents or great grandparents whose ancestral geographical origins include areas where the trait or disease is common.<sup>47</sup>

### 3. Bone Density and Race

Similarly, some researchers continue to argue that there is a correlation between race and biology in bone density. According to the first sentence of an article in a 2008 issue of the *Journal of Nutrition*:

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Latin American, Native American, and Mediterranean heritage.” U. MD. MED. CTR., *supra* note 36.

<sup>43</sup> U. MD. MED. CTR., *supra* note 36.

<sup>44</sup> See Braun et al., *supra* note 9, at 1425-26 (arguing that “[i]n the case of sickle cell disease, it would be best to work from symptoms rather than racial assumptions and to enquire about geographic ancestry since sickle cell disease is more prevalent in populations from the Mediterranean region, sub-Saharan Africa, and the Indian subcontinent.”).

<sup>45</sup> *Id.*

<sup>46</sup> Feldman et al., *supra* note 31, at 374. They argue that social race “provides information about the social circumstances and lifestyle of patients.” *Id.* But even this description ignores the heterogeneity and class differences within populations raced as black in America.

<sup>47</sup> “A ‘black’ person walking into a Boston, Massachusetts clinic could easily be the child of a recent immigrant from Ethiopia or Brazil who has a genetic makeup as well as cultural and environmental exposures that differ significantly from the descendents of [nineteenth] century U.S. slaves from the western coast of Africa.” Braun et al., *supra* note 9, at 7. Another researcher wrote: “In the case of sickle cell disease, it would be best to work from symptoms rather than racial assumptions, and to enquire about geographic ancestry.” *Id.* at 8. Thus Feldman et al. conclude that a better approach is to identify “all contributions to a patient’s ancestry” when “diagnosing and treating disease with genetic influences.” Feldman et al., *supra* note 31, at 374.

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“Diet and race are important predictors of areal bone mineral density (aBMD) and fracture risk.”<sup>48</sup> The introductory sentence reads like a general fact; it is not footnoted.<sup>49</sup> Under the subheading, *Racial differences in bone density*, the authors write:

African American men and women have higher aBMD than other racial groups, including American white, Asian, Hispanic, and Native Americans. Such differences are attenuated but still generally persist when aBMD data are adjusted for weight, bone size, and other covariates, such as physical activity, calcium intake, smoking, and alcohol use.<sup>50</sup>

The authors base these statements on earlier studies of fracture risk and bone density among various ethnic groups.<sup>51</sup> These earlier studies are the basis for the different measurement standards to determining bone density that were applied to my friend.

The same year as the aforementioned study, biologist and feminist scholar Anne Fausto-Sterling asked whether accepted studies on bone density that report notable differences based on race *really* reflect racial differences and if so, what this means “biologically and socially.”<sup>52</sup> She looked at a sample of published research to determine how researchers defined race in studies examining claims about the relationship between race and bones. She notes that many early papers discussing bone density cite to Mildred Trotter’s work in the 1960s and 1970s,<sup>53</sup> but new technology prompted a shift from Trotter to large scale studies.<sup>54</sup> Fausto-Sterling takes issue with these modern studies, arguing

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<sup>48</sup> Marcella D. Walker et al., *Race and Diet Interactions in the Acquisition, Maintenance, and Loss of Bone*, 138 J. NUTRITION 1256S, 1256S (2008).

<sup>49</sup> Marc C. Hochberg, *Racial Differences in Bone Strength*, 118 TRANSACTIONS OF THE AM. CLIN. & CLIMATOLOGICAL ASS’N 305, 308-10 (2007). (discussing several studies that support the claim that whites have lower bone mineral density than blacks).

<sup>50</sup> Walker et al., *supra* note 48, at 1256S-57S.

<sup>51</sup> *Id.*

<sup>52</sup> Fausto-Sterling, *supra* note 4, at 659. Her question applies to biomedical, biotechnological, and genomic research generally, but this article only focuses on biomedical or medical research.

<sup>53</sup> Trotter was a well-known anatomist and anthropologist whose professional career spanned from 1922 until 1984. “Her research led to discoveries about the structure and distribution of hair, and the growth, racial and sexual differences, and aging of the human skeleton. Additionally, her work in skeletal biology led to the creation of formulas to estimate stature based on the lengths of long leg bones.” *Missouri Women in the Health Sciences: Mildred Trotter*, WASH. U. ST. LOUIS SCH. OF MEDICINE, <http://beckerexhibits.wustl.edu/mowihsp/bios/trotter.htm> (last visited Dec. 7, 2010).

<sup>54</sup> Fausto-Sterling, *supra* note 4, at 661.

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they “reveal[] profound inconsistencies in the definitions and modes of ascertainment of racial categories, a lack of theory about why race might be an important study variable, and no clear rationale about how race might exert effects on bone biology.”<sup>55</sup>

Yet papers addressing bone density into the early twenty-first century still began with the presumption that race-based differences in bone density are “incontrovertibly established.”<sup>56</sup> But as Fausto-Sterling argues, based on her research, these studies are suspect because the scientists used race uncritically.<sup>57</sup> She is not alone in her criticism, which applies equally to other medical research studies.

### B. Debunking the Link between Race and Biology

In the late 1990s American social scientists spoke out strongly against connecting race with biology. The Executive Committee of the American Anthropological Association (AAA) after studying the issue concluded: “present-day inequalities between so-called ‘racial’ groups are not consequences of their biological inheritance but products of historical and contemporary social, economic, educational, and political circumstances.”<sup>58</sup> The AAA’s statement reflects the concerns expressed

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<sup>55</sup> *Id.* at 662.

<sup>56</sup> *Id.*

<sup>57</sup> She writes that social notions about race “produce-[] the biological . . . [b]y providing a different angle of vision on claimed racial differences.” *Id.* at 658. The accepted scientific assumption for bone disease in adults is that white and Asian women are at highest risk, followed by Hispanic women, then by white and Asian men, then Hispanic men, then black men. Black women have rates similar to white men. *Id.*

Further, as my colleague Amanda Pustilnik points out, even if these findings were real, their significance is open to question. If what matters is fracture risk, and fracture risk results from current bone density—not percentage of bone loss from baseline—then a starting point would seem irrelevant. But if a starting point mattered, then it seems that the doctor would want to compare that patient’s current results to her own, individual scan taken at Time 1. There must be all kinds of starting point bone density differences, depending on childhood nutrition, individual genetics, childhood sports, etc. So not only is the “racial” dimension of this claim questionable, the whole starting point position seems to be a pure nonsense dimension.

<sup>58</sup> *Statement on “Race,”* AM. ANTHROPOLOGICAL ASS’N (adopted May 17, 1998), <http://www.aaanet.org/stmts/racepp.htm>. A few years earlier the AAA adopted a resolution that read in part: “differentiating species into biologically defined ‘races’ has proven meaningless and unscientific as a way of explaining variation.” *Statement on “Race” and Intelligence,* AM. ANTHROPOLOGICAL ASS’N (adopted Dec. 1994), <http://www.aaanet.org/stmts/race.htm>. Almost a decade later, social scientist Troy Duster repeated this concern about the “current understandings of the relationship between race and disease . . . [and the increasing reliance on] genetically oriented biomedical scientists . . . to define and identify causes for a wide-ranging set of problems—from alcoholism to gender and racial health disparities.” Fausto-Sterling, *supra* note 4, at 657 (citing the

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two years earlier by British researchers attempting to fashion a framework for the “classification of ethnic or cultural groups.”<sup>59</sup> They argued that when medical researchers use ethno-racial categories, they must clearly establish the biological correlation if they believe ethno-race clearly explains the differences in disease patterns.<sup>60</sup> Unlike the British model, the later AAA statement contains no qualifiers, no circumstances when the use of ethno-racial classifications is warranted. This absolutist approach is a sticking point with some researchers, who believe that there are instances where ethno-race categories can function as both an *ascriptive* factor (“to identify the causal mechanisms involved and to select clinical interventions”)<sup>61</sup> and as a *descriptive* factor (“to document progress in the health status of populations”).<sup>62</sup> Other researchers argue that ethno-race is only relevant in biomedical research as a descriptor.<sup>63</sup> But even in this instance researchers have yet to agree on how to define ethno-racial categories.

Two articles that appeared in the September 2007 issue of *PLoS Medicine*, a peer-reviewed journal published by the Public Library of Science, illustrate the ongoing debate in the medical research community about the use of ethno-race. The first, written by Lundy Braun (with Fausto-Sterling and other co-authors), begins by drawing the distinction between the importance of the *descriptive* use of racial and ethnic categories, as negative health outcomes differ among racial and ethnic groups, and the widespread *ascriptive* use of U.S. census ethno-racial categories in biomedical research. The misuse of ethno-racial categories in the latter instance, Braun argues, is reinforced by the National Institutes of Health’s (NIH) funding regulations designed to ensure greater inclusion of racial/ethnic minorities in clinical research. These

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2005 inaugural address of Troy Duster, *Comparative Perspectives and Competing Explanations: Taking on the Newly Configured Reductionist Challenge to Sociology*, AM. SOC. REV 1 (2006).

<sup>59</sup> Kwame McKenzie, *Describing Race, Ethnicity, and Culture in Medical Research*, 312 BRIT. MED. J. 1054 (1996) (The U.K. adopted categories used by the Office of Population Censuses and Surveys for use in the 1991 census); Mike Pringle & Ian Rothera, *Practicality of Recording Patient Ethnicity in General Practice: Descriptive Intervention Study and Attitude Survey*, 312 BRIT. MED. J. 1080, 1082 (1996) (ethnicity should be self-defined and is of questionable value in general practice).

<sup>60</sup> McKenzie, *supra* note 59.

<sup>61</sup> George T.H. Ellison et al., *Racial Categories in Medicine: A Failure of Evidence-Based Practice?*, 4 PLOS MED. 1434, 1434 (2007). In other words, “not using basically social categories to produce biological *attribution* of causes.” Braun et al., *supra* note 9, at 1427.

<sup>62</sup> Braun et al., *supra* note 9, at 1427. In other words, using race descriptively “to identify differences in health and health care that warrant further investigation and intervention.” Ellison et al., *supra* note 61, at 1424.

<sup>63</sup> See *infra*, notes \_\_\_ and accompanying text.

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regulations use the racial and ethnic categories as defined by the U.S. Office of Management and Budget (OMB)'s Directive No. 15<sup>64</sup> to measure inclusion rates. The result is “poorly defined racial categories [that become] . . . reified in biomedical research practices.”<sup>65</sup>

Consider, for example, the classification problem that might arise if a clinical protocol calls for the physician to identify the race of a man who immigrated to the United States at a young age and self-identifies as Cape Verdean.<sup>66</sup> “The large Cape Verdean population in New England resists any simple categorization. The inhabitants are the descendents of Portuguese colonists, former slaves, explorers, and sailors of various nationalities.”<sup>67</sup> Given this reality, is the subject black? Is the subject “now African American or should [the physician] consider [the subject's] health needs from the perspective of his immigrant status?” The data on response to therapy seem to suggest that hypertension in blacks is somehow special, implying a separate genetic factor for

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<sup>64</sup> *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*, U.S. DEP'T HEALTH & HUM. SERVS. (amended Oct. 2001), [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). For a discussion of this point, see Braun et al., *supra* note 9, at 1424. Braun mentions the Institute of Medicine's (IOM) definition of race, as an example of how “granting agencies' regulations do little to clarify the extent to which racial and ethnic categories are intended to capture biological, cultural, or social dimensions of human diversity.” *Id.* (citing INSTITUTE OF MEDICINE, *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE* (2003)). The American Anthropological Association describes OMB Directive 15 as follows:

The Statistical Policy Division, Office of Information and Regulatory Affairs, of the Office of Management and Budget (OMB) determines federal standards for the reporting of “racial” and “ethnic” statistics. In this capacity, OMB promulgated Directive 15: Race and Ethnic Standards for Federal Statistics and Administrative Reporting in May, 1977, to standardize the collection of racial and ethnic information among federal agencies and to include data on persons of Hispanic origins, as required by Congress. Directive 15 is used in the collection of information on “racial” and “ethnic” populations not only by federal agencies, but also, to be consistent with national information, by researchers, business, and industry as well.

Directive 15 described four races (i.e., American Indian or Alaskan Native, Asian or Pacific Islander, Black, and White) and two ethnic backgrounds (of Hispanic origin and not of Hispanic origin). The Directive's categories allowed collection of more detailed information as long as it could be aggregated to the specified categories.

*American Anthropological Association Response to OMB Directive 15: Race and Ethnic Standards for Federal Statistics and Administrative Reporting*, AM. ANTHROPOLOGICAL ASS'N (Sept. 1997), <http://www.aaanet.org/gvt/ombdraft.htm>.

<sup>65</sup> Braun et al., *supra* note 9, at 1423-24.

<sup>66</sup> *Id.* at 1424.

<sup>67</sup> *Id.* at 1424.

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blacks.”<sup>68</sup>

Given the historical misuse of ethno-racial categories in ways that perpetuate notions about racial inferiority,<sup>69</sup> Braun asks whether ethno-race is a useful factor to consider in determining medical care.<sup>70</sup> Her concern is that physicians, relying on race-based biomedical research, will make diagnoses or risk assessments and treatment decisions based on a person’s race rather than using a procedure that considers factors like environment, family history, stress, and other socioeconomic contributors to health disparities.<sup>71</sup> She argues that because racial categories are deceptively simple, they conceal diverse internal populations. For example, a person with black, white, and Native American ancestors may self-identify as black, as would a recent immigrant from Ethiopia. Rather than work from racial assumptions, some grounded in geographic ancestry, Braun, like Feldman and his co-authors, argues that researchers should focus on individual symptoms.<sup>72</sup> Otherwise, “once race is presumed . . . clinical clues can become invisible.”<sup>73</sup>

To counter this troubling trend, Braun recommends educating medical researchers and practitioners about cultural competency, the historical misuse of racial categories, the current debates about the validity of ethno-race in medicine, the limits of racial categorization in the medical context, population race versus individual race, and geographical genetic variation.<sup>74</sup> While she acknowledges the need for “an international consensus” on the use of ethno-racial categories in science, she argues for more immediate action by the NIH in reevaluating its policies on racial categorization, and by medical schools in improving their instruction on race in medicine.<sup>75</sup>

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<sup>68</sup> The authors explain: “African Americans suffer at rates 3.5 times those of Nigerians living in Africa, although African Americans experience only 0.75 the rates of Germans in Germany. Which category matters more for Grace’s patient, country of origin or social status in the adopted nation?” *Id.* (citations omitted).

<sup>69</sup> *Id.* at 1424-25.

<sup>70</sup> *Id.* at 1425.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 1426. They also discuss the idea of cultural competency, espoused in some quarters, which encourages clinicians to “familiarize themselves with the history of the particular communities they serve.” Conceding that while the approach may have some benefits (“brings greater attention to the attitudes and behaviors that patients may bring to the clinical encounter”), it also brings the danger that the clinician may see patients as “types” rather than individuals. *Id.* at 1426.

<sup>73</sup> *Id.* at 1425-26.

<sup>74</sup> *Id.* at 1426-27.

<sup>75</sup> *Id.* at 1427. Braun ends by restating the distinction drawn by anthropologist Michael Montoya between using ethno-race descriptively and ascriptively. *Id.*



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Like Braun, medical anthropologist George T.H. Ellison and his co-authors recognize the challenges to instituting more precise attributive factors; and the need to distinguish between the *descriptive* use of ethno-racial categories, and the *attributive* use of such categories,<sup>76</sup> but Ellison and his co-authors find Braun’s proposals problematic. First, they point to the “lack of consensus about what race and ethnicity mean and how these [categories] should be operationalised.”<sup>77</sup> Second, while researchers know that ethno-racial categories are inaccurate, they adopt a “pragmatic” approach to NIH requirements designed to insure greater representation of ethno-racial groups in research studies.<sup>78</sup> Ellison et al., like Braun, worry that the crude ethno-racial categories that NIH uses to monitor inclusion of racial and ethnic minorities in clinical trials and to describe differences in health care and health outcomes actually may be harmful. They warn that NIH policies that use OMB-like ethno-racial categories for these purposes may undermine efforts to ascertain “more precise *attributive* evidence.”<sup>79</sup> Ellison and his co-authors propose that ethno-racial categories be used only as “*descriptive* variables in different scientific, clinical, and social contexts.”<sup>80</sup> They argue that other genetic, cultural, or structural markers need to be identified and developed to provide a more precise causal connection of the disparities in health and health care.”<sup>81</sup>

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<sup>76</sup> Ellison et al., *supra* note 61, at 1435.

<sup>77</sup> *Id.* at 1434. Ellison concedes this lack of consensus means that “researchers and practitioners may conflate the utility of racial and ethnic categories for sampling diverse study populations with their ability to identify and address aetiological variation therein.” *Id.* Ellison argues that Braun’s proposal “would require unprecedented agreement amongst a comprehensive international consortium of funders and providers” about the use of ethno-racial categories. *Id.* at 1436.

<sup>78</sup> *Id.* They concede that “[t]he use of crude socio-political categories of race and ethnicity to describe variation in health risks and health needs, and to attribute these differences to innate genotypic and socio-cultural factors, has a long and discredited history.” *Id.* at 1435. In an effort to avoid stigmatizing particular racial or ethnic groups, some researchers “adopt the more socially acceptable term ‘ethnicity’ in preference to ‘race,’” while other researchers adopt “crude socio-political classifications” such as the OMB categories. *Id.*

<sup>79</sup> *Id.* While racial and ethnic categories are helpful for descriptive purposes, Ellison argues that “researchers and clinicians do need to be encouraged to use more specific attributive markers of genotype, culture, and structural disadvantage wherever appropriate.” He argues that the use of racial and ethnic categories in describing differences in health risks and outcomes results in the same crude categories being misattributed as the cause of health differences. *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

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### C. Stress and Black Americans: Does Social Race Have a Biological Component?

The foregoing discussion does not squarely address another question, whether there is validity in doing research on different race-based outcomes that flow from social and environmental factors. Arguably there could be a biological, yet socially created reality to race differences in health. This section explores what might be required to make such research useful.

Medical experts agree that stress can affect the onset, progression, and severity of illness, and that racism and race-related stress have an impact on health.<sup>82</sup> Stress literature suggests that acute and chronic experiences with racism have different effects on illness and disease.<sup>83</sup> The strongest association has been found between racism and negative mental health outcomes.<sup>84</sup> Some studies have also found a relationship between racism and certain physical health risks, conditions, or behaviors.<sup>85</sup>

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<sup>82</sup> David R. Williams & Selina A. Mohammed, *Discrimination and Racial Disparities in Health: Evidence and Needed Research*, 32 J. BEHAV. MED. 20, 27 (2009). Williams and Mohammed explain how, according to stress literature, stress affects the onset, progression, and severity of illness, and describe several health conditions that may be affected by stress, including five physiological categories where stress has been shown to affect symptoms (neuroendocrine system, cardiovascular system, gastrointestinal system, pain sensitivity and chronic pain, and immune function). They encourage future research that “focus[es] its attention on those outcomes where prior research has documented that stress in general is linked to health.” *Id.* at 38; Elizabeth Brondolo et al., *Race, Racism and Health: Disparities, Mechanisms, and Interventions*, 32 J. BEHAV. MED. 1 (2009). Exposure to racism, in any form, may initiate a series of “acute and enduring changes in cognition, affect, behavior, and psychophysiological responses.” *Id.* at 3; Yin Paradies, *A Systematic Review of Empirical Research on Self-Reported Racism and Health*, 35 INT’L J. EPIDEMIOLOGY 888, 893 (2006) (reporting that a group of twenty-six studies revealed a significant association between self-reported racism and 44% of certain health outcomes, including blood pressure, birth weight, BMI/obesity, and mortality; 36% of all negative health outcomes were significantly associated with racism).

<sup>83</sup> Williams & Mohammed, *supra* note 82, at 33.

<sup>84</sup> *Id.* at 22; Paradies, *supra* note 82, at 892.

<sup>85</sup> Shawn O. Utsey et al., *Effect of Ethnic Group Membership on Ethnic Identity, Race-Related Stress and Quality of Life*, 8 CULTURAL DIVERSITY & ETHNIC MINORITY PSYCHOL. 366, 368 (2002) [hereinafter *Effect of Ethnic Group Membership*] (effect of race-related stress response on the immune, neuroendocrine, and cardiovascular systems); Shawn O. Utsey et al., *Race-Related Stress, Quality of Life Indicators, and Life Satisfaction Among Elderly African Americans*, 8 CULTURAL DIVERSITY & ETHNIC MINORITY PSYCHOL. 224, 225 (2002) [hereinafter *Race-Related Stress*] (racism has been associated with stress-related diseases such as hypertension, coronary heart disease, and cancer, as well as psychological ailments including depression.); Paradies, *supra* note 82, 893 (measured physical health outcomes including blood pressure, birth weight, BMI/obesity, and mortality, finding that 44% of negative physical health outcomes were “significantly associated with self-reported racism.”).

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Overall, the associations between racism and health vary among different ethno-racial groups, with black Americans experiencing the strongest associations and white Americans experiencing the weakest associations, even when socioeconomic factors are taken into account.<sup>86</sup> It is important to note, however, that whites generally experience less racism than non-whites, which may explain the different race-related stress levels.<sup>87</sup> Nevertheless, several comparative studies “found that self-reported racism was related to ill-health for African Americans and Latinos/as, but not [w]hites.”<sup>88</sup> Other studies found inverse associations, leading one researcher to conclude that “the association between self-reported racism and health-related outcomes for studies that included [w]hite participants is comparable with the findings of studies involving other ethnic/racial groups.”<sup>89</sup>

While factors like intensity, frequency, and duration of the stressor can affect negative outcomes,<sup>90</sup> further research is needed to determine whether racism is analogous to other stressors;<sup>91</sup> whether there is an association between mature stages of racial identity and less race-related stress;<sup>92</sup> and whether racial identity may modify the association between self-reported race and health.<sup>93</sup> Research also is needed to determine the additional long-term effects of race-related stress.<sup>94</sup> Further illustrating the complexity of race in biomedicine, researchers

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<sup>86</sup> Deidre Franklin-Jackson & Robert T. Carter, *The Relationships Between Race-Related Stress, Racial Identity, and Mental Health for Black Americans*, 33 J. BLACK PSYCHOL. 5, 6 (2007) (studies linked racism to various psychological symptoms, and further notes the hypothesis among scholars and researchers that Blacks may experience racism as a chronic or life event stressor); Hope Landrine et al., *Conceptualizing and Measuring Ethnic Discrimination in Health Research*, 29 J. BEHAV. MED. 79, 79 (2006) (“[m]inorities who perceive and report individual-level ethnic discrimination have more physical and psychiatric symptoms and problematic health behaviors than their White and than their no-discrimination minority cohorts.”); Utsey et al., *Effect of Ethnic Group Membership*, *supra* note 85, at 366-67 (African Americans have higher measures of race-related stress than Whites and Asians); Chalsa M. Loo et al., *Measuring Exposure to Racism: Development and Validation of a Race-Related Stressor Scale (RRSS) for Asian American Vietnam Veterans*, 13 PSYCHOL. ASSESSMENT 503, 525 (2001).

<sup>87</sup> Paradies, *supra* note 82, at 891.

<sup>88</sup> *Id.*

<sup>89</sup> Paradies, *supra* note 82, at 893.

<sup>90</sup> Williams & Mohammed, *supra* note 82, at 35-38.

<sup>91</sup> Williams & Mohammed, *supra* note 82, at 33.

<sup>92</sup> Franklin-Jackson & Carter, *supra* note 86, at 18-19.

<sup>93</sup> Paradies, *supra* note 82, at 893.

<sup>94</sup> Utsey et al., *Race-Related Stress*, *supra* note 85, at 231. The authors stress that professionals need to understand how racism as a chronic stressor affects quality of life. *Id.* While coping strategies and socialization are specified by Utsey et al. as potential mediating factors, in another article, Utsey mentions a positive association between ethnic identity and quality of life. Utsey et al., *Effect of Ethnic Group Membership*, *supra* note 85, at 374.

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acknowledge problems in conceptualizing and measuring racism.<sup>95</sup>

While early stress studies focused on health disparities between different ethno-racial groups, new research suggests that there are also differences *within* each racial group.<sup>96</sup> Thus, some commentators suggest that future research should consider both the differences *between and within* groups to determine whether ethnicity is “a moderating factor in the relationship of psychosocial stressors, such as racism, to health outcomes.”<sup>97</sup> These commentators also suggest that future studies focus on the varying contexts in which racism occurs.<sup>98</sup>

The stress studies literature suggests that under some circumstances self-identified ethno-race, even though socially constructed, may be valid as a measure in certain scientific research. But even here, simplistic ethno-racial categories are inadequate measures. Following early studies that found “perceived racial discrimination contributed significantly to psychiatric symptoms among African Americans,” some researchers looked for a reliable measure of perceived racial discrimination.<sup>99</sup> Each of these measures acknowledges that stress

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<sup>95</sup> “One of the most challenging issues in the study of racism has been its conceptualization and measurement. . . . [Thus] studies contrasting the prevalence and health effects of different categories of racism/ethnic discrimination are also needed, and this will require alterations in approaches to conceptualizing and measuring racism.”

Brondolo et al., *supra* note 82, at 3.

<sup>96</sup> Brondolo et al., *supra* note 82, at 3.

<sup>97</sup> *Id.* Examples of psychophysiological reactivity cited were cortisol, blood pressure, and heart rate responses. *Id.* at 4. The authors suggest that future studies should focus on different categories of racism (cultural, institutional, individual) as well as the varying contexts in which racism occurs (implicit or explicit). *Id.*

<sup>98</sup> *Id.* For additional commentary on the need for future research in this area, see David R. Williams et al., *The Concept of Race and Health Status in America*, 109 PUB. HEALTH REP. 26 (1994) (discussing the potential effects of racism and racial discrimination on health outcomes, particularly stress and hypertension, and the need for further research)

<sup>99</sup> Loo et al., *supra* note 86, at 503-04. A Race-Related Stressor Scale (RRSS) was proposed that created three categories of race-related stressors: (1) racial prejudice and stigmatization (direct experiences of perceived discrimination or exclusion), (2) bicultural identification and conflict (identifying with a racial or ethnic minority and culture), and (3) racist environment (witnessing racist or discriminatory behavior). *Id.* at 504-05. The study applied this measure to Asian American Vietnam veterans finding that exposure to one, or a combination of, each of the three categories above contribute to Post Traumatic Stress Disorder (PTSD) and general psychiatric symptoms. *Id.* at 514-15. Another research group, concerned about the failure of early stress studies to measure the *frequency and appraisal* of stressful events offered another measure, the General Ethnic Discrimination Scale (GEDS) that looks at both frequency and appraisal of discriminatory events across all ethnic groups based on the stress coping model. Landrine et al., *supra* note 86, at 80-81. Still another research group used the Index of Race-Related Stress (IRRS) that in its “brief version” measures cultural, institutional, and individual racism. Utsey et al., *Effect of Ethnic Group Membership*, *supra* note 85, at

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resulting in physical and mental illness is not triggered by social race alone, but is heavily linked to individual perceptions of race, the extent of racial and cultural self-identification and how individuals experience and process racist or discriminatory behavior. Further, the stress response to racism and discrimination is associated with psychological and physiological reactions like anxiety and paranoia, and the physiological responses primarily involve the immune, neuroendocrine, and cardiovascular systems.<sup>100</sup> Studies on race-related stress that only take race into account would be, according to these articles, fatally flawed.

As the race-related stress studies suggest, descriptive race in its crudest form may overlook important differences within categories. Even if stress is a circumstance where ascriptive ethno-race may contribute to a medical outcome, it is important to look at other contributing factors. Thus, more thoughtful use of ethno-race as either a descriptor or ascriptor should be the goal of any biomedical research-related guideline or regulation.

Braun and Ellison, in their critiques of race's relevance in biomedical research, acknowledge the potential influence that biomedical journals have on the use of ethno-racial categories.<sup>101</sup> A few high impact

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<sup>100</sup> Utsey et al., *Effect of Ethnic Group Membership*, *supra* note 85, at 368. Previous studies found the psychological effects of stress include anxiety and paranoia, and the physiological responses primarily involve the immune, neuroendocrine, and cardiovascular system. *Id.* Ethnic group membership was found to have a statistically significant effect on race-related stress, ethnic identity score, and quality of life scores. African Americans had higher scores for race-related stress, ethnic identity, and the psychological well-being subscale of the quality of life measure. The results further indicated that racial identity and cultural racism stress both significantly predicted qualities of life. As might be expected, cultural racism was inversely related to quality of life. Notably, the study indicated that ethnic identity was the best predictor of quality of life, which implies that ethnic identity is related to psychological and physical health. *Id.* at 372-75. Future studies need to account for a range of other factors that affect how race-related stress impacts individuals such as socialization, coping strategies, cultural identity, individual perception, the types of racism, environmental factors and traditional stressors.

<sup>101</sup> Braun points out that journals approach this question from one of three perspectives. Some journals accept self-identified race or ethnicity is an acceptable proxy for genetic makeup; others state that race should not be used in genetic research because of the genetic variation within self-identified populations; and still others adopt a middle position whereby race can be used to ensure diversity in studies, but not as a proxy for genetic variation. Braun et al., *supra* note 9, at 1424. The authors cite a recent study finding “commonly used ethnic labels are both insufficient and inaccurate representations of the inferred genetic clusters and that drug-metabolizing profiles . . . differ significantly among the clusters.” *Id.*

Ellison advocates advancing his proposal through biomedical journals, noting,

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medical journals have stepped into this debate. The next section examines and critiques both medical journal and federal guidelines on the use of ethno-race in biomedical research.

### III. Guidelines on Race and Ethnicity

#### A. Journal Guidelines

Some experts agree with Braun and Ellison about the role high impact scientific journals can play in discouraging the misuse of race in medical research, but they disagree about the goal and focus of journal guidelines. Stacie Geller, for example, argues that these journals need to adapt their editorial guidelines to reinforce the importance of greater compliance with federal guidelines aimed at promoting more diversity among clinical study participants.<sup>102</sup> Fausto-Sterling, on the other hand, advocates even stronger measures. She argues that editors of scientific journals and those who review articles for these journals should require that researchers define and justify their use of racial categories, especially since other factors like socioeconomic status, geography, and individual life cycle may be better predictors of specific disease patterns.<sup>103</sup>

To date, three major English language scientific academic publications, the *British Medical Journal*, *Nature Genetics* and the *Journal of the American Medical Association*, have announced guidelines on the use of race and ethnicity in medical research. With the exception of *Nature Genetics*, these journal guidelines are aspirational,

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however, that some journals are resistant to guidelines, and that the guidelines have not significantly affected the content of the journals that do have them. Ellison et al., *supra* note 61, at 1436. According to Ellison, “648 journals signed up to the International Committee of Medical Journal Editors’ *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*, which recommend that ‘When authors use variables such as race or ethnicity, they should define how they measured the variables and justify their relevance.’” *Id.* He calls for an international consensus in the biomedical community to support guidelines that (1) improve racial and ethnic categories as descriptive factors; (2) advocate for the inclusion of specific genotypical, cultural, and structural attributive factors; and (3) “generat[e] evidence from population studies of racial and ethnic groups that can be used to improve the care of individual patients from these groups across different social and clinical contexts.” *Id.*

<sup>102</sup> Stacie E. Geller et al., *Adherence to Federal Guidelines for Reporting of Sex and Race/Ethnicity in Clinical Trials*, 15 J. WOMEN’S HEALTH 1123, 1130-31 (2006). She also argues that funding agencies must engage in greater scrutiny of the clinical trials they support to ensure equitable enrollment among gender and race/ethnicity. *Id.*

<sup>103</sup> Fausto-Sterling, *supra* note 4, at 670.

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not mandatory. A fourth journal, the *New England Journal of Medicine*, entertained a debate on the subject but adopted no guidelines. Most guidelines advocate for increased clarity in why ethno-race is being considered, the rationale behind the ethno-racial groupings, and the method of subject assignment. This section critiques these guidelines to determine whether any contain useful restrictions Congress might adopt to discourage the inappropriate use of ethno-race in federally funded biomedical research.

The *Journal of the American Medical Association (JAMA)* is the only journal to expressly advocate the use of self-identified race in biomedical research.<sup>104</sup> According to Margaret Winkler, Deputy Editor of *JAMA*, the guidelines elaborate on and clarify the published guidelines of the International Committee of Medical Journal Editors (CMJE) that advise authors who use ethno-racial variables to “define how they measured the variables and justify their relevance.”<sup>105</sup> The *JAMA* guidelines add that “authors should describe who designated race and/or ethnicity for an individual [noting that] *self-designation generally is preferred*.”<sup>106</sup> Rather than discourage the use of ethno-racial labels in research, the *JAMA* guidelines support subject self-identification of ethno-racial identity which, as mentioned previously and discussed below, is a poor proxy for genetic variation.<sup>107</sup>

But a subject’s self-identified ethno-racial status may be different from that individual’s bio-geographic ancestry based “on a range of historical, cultural and sociopolitical factors.”<sup>108</sup> My friend, for example, self-identifies as black (remote African ancestry), while her bio-geographic ancestry may more strongly correspond to her remote European ancestry. Thus, self-identification as a method to assign ethno-racial categories (and sometimes inappropriately infer genetic makeup) is limited because it may only provide a partial view of the individual’s geographic genetic ancestry.<sup>109</sup> Nevertheless, self-identified race and

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<sup>104</sup> Margaret A. Winkler, Editorial, *Measuring Race and Ethnicity: Why and How?*, 292 *JAMA* 1612, 1614 (2004).

<sup>105</sup> *Id.* (citing INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, UNIFORM REQUIREMENTS FOR MANUSCRIPTS SUBMITTED TO BIOMEDICAL JOURNALS: WRITING AND EDITING FOR BIOMEDICAL PUBLICATION, sec. IV.A.6.a (updated Nov. 2003), <http://www.icmje.org/#prepare>). The CMJE guideline statement emphasizes the need for clarity in racial categorization. *Id.*

<sup>106</sup> *Id.* (emphasis added).

<sup>107</sup> Caulfield et al., *supra* note 12, at 8.2. For a discussion of this point, see *supra* footnotes 11, 19, 73 and accompanying text.

<sup>108</sup> Sandra Soo-Jin Lee et al., *The Ethics of Characterizing Difference: Guiding Principles on Using Racial Categories in Human Genetics*, 9 *GENOME BIOLOGY* 404, 404.2 (2008) (Statement 7).

<sup>109</sup> *Id.* at 404.2.

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bio-geographic ancestry are important in studying health disparities.<sup>110</sup>

Second, the *JAMA* guidelines state that “[a]uthors should indicate whether the options for [racial and ethnic] designation were closed or open.”<sup>111</sup> Winkler notes that while open-ended options potentially provide a more accurate description of individual ethno-racial identity, open-ended self-reported ethno-race is difficult to categorize for research purposes. Knowing, for example, that a clinical subject self-identifies as having Hawaiian, Chinese, English, and Korean ancestry helps establish the diversity of enrollees, but outside of a study of populations in Hawaii this level of self-identification will result in too small a sample group to provide researchers with useful information. Winkler, however, offers no solutions for dealing with problematic open-ended options.

The guidelines further suggest that researchers should make ethno-racial coding in studies more “transparent” by disclosing the options for racial categories used by researchers, how these options were established, and what subcategories are included in the study.<sup>112</sup> Thus this guideline, which seems to favor closed option ethno-racial designations for coding purposes, undercuts the first and supposed primary guideline goal, clarity in racial categorization. Clarity in ethno-racial designations also is relevant in monitoring who has access to clinical studies, a point addressed in part by the last *JAMA* guideline.

The *JAMA* guidelines also state that authors should justify why they believe ethno-race is “relevant to the particular study.”<sup>113</sup> The goal of this provision is to encourage researchers to more critically consider the relevance of ethno-race as factors in the study<sup>114</sup> or, in other words, to analyze whether the ascriptive use of ethno-race is appropriate. Thus *JAMA* encourages researchers to directly measure other social and environmental factors as causes.<sup>115</sup>

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<sup>110</sup> *Id.*

<sup>111</sup> Winkler, *supra* note 104, at 1614. The guideline continues: “If the options were closed, authors are asked to provide what the options were, whether categories were combined, and, if so, how.” *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.* The authors should state their rationale if they use race or ethnicity as proxies for unknown, or hard to measure variables. The editorial gives the following examples of social and environmental factors that should be measured directly: “socioeconomic status, education, urban vs. rural location, or income region by zip code.” *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.* at 1614 (“determine whether an outcome is truly related to ethno-race (as defined by the study) or to other factors with a closer relationship to the causal pathway.”).



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By not renouncing the use of race as a proxy for genetic similarity, the *JAMA* guideline, while an improvement, only hints at the potential for misuse of ethno-racial labels in research. Under the guideline, race is a permissible proxy for other difficult to measure variables, so long as the rationale for doing so is clearly stated. But Winkler cites no examples of situations where race would be an acceptable substitute for these difficult to measure and unspecified variables, a troublesome omission.<sup>116</sup>

Further, Winkler’s reasoning seems circular. She concedes that race is a social construct with little or no scientific value but argues that ethno-racial self-identification may have some unspecified value in biomedical research. Because the *JAMA* guidelines provide little real guidance researchers are likely to continue following old familiar patterns, relying on older studies that used race inappropriately.

As mentioned earlier, the *British Medical Journal (BMJ)* was the first high impact medical journal to publish guidelines on the use of ethno-race in biomedical research. The journal offers three major guidelines; the first two are meant to encourage authors to explain “the logic behind their ‘ethnic’ groupings.”<sup>117</sup> First, the journal urges “authors . . . to use accurate descriptions” when employing ethno-racial terminology.<sup>118</sup> In explaining the need for these guidelines, *BMJ* discussed how ethno-race terminology is subject to culture, political debates and imperatives.<sup>119</sup> Since ethno-race terms are forever changing, the journal reasons, authors should provide descriptions with racial terminology so that future researchers will be able to more reliably compare past results to future ones.<sup>120</sup>

Secondly, *BMJ* announced that, henceforth, racial or ethnic descriptions should reference the method behind these groupings.<sup>121</sup> Thus, *BMJ* encourages specific description of ethno-racial categories, as well as a notation of how the groupings were assigned. The journal used as an example of the first two guidelines, the ethno-racial self-identified label “black Caribbean” instead of “black.”<sup>122</sup>

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<sup>116</sup> *Id.* at 1614. The editorial states that the researchers should try to measure as many variables as possible directly, such as socioeconomic status, education, urban versus rural locations, or income region by ZIP code. *Id.* at 1614.

<sup>117</sup> Editorial, *Ethnicity, Race, and Culture: Guidelines for Research, Audit, and Publications*, 312 *BRIT. MED. J.* 1094 (1996).

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

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The third guideline provides that any ethno-racial “[c]ategorisation . . . should relate to the type of hypothesis under investigation.”<sup>123</sup> The *BMJ* notes that “race has limited biological validity,”<sup>124</sup> thus categories based on genetic make-up, for example, should be used ascriptively in studies assessing health risks, whereas ethno-racial categories may be more helpful descriptively in studies assessing health services. If researchers do not know which, among race, ethnicity, or culture, will be the most powerful determinant of the outcome, *BMJ* advises them to measure each factor. Thus the *BMJ* encourages researchers to collect a range of information, including “genetic differences, self-assigned ethnicity, observer assigned ethnicity, country or area of birth, years in country of residence, and religion.”<sup>125</sup> These guidelines aim at ensuring that biomedical research is more credible in the future.<sup>126</sup>

Whereas *JAMA* and *BMJ* published their guidelines “hoping” that authors would “try” to follow them, only one journal, *Nature Genetics*, stated that their guidelines are mandatory.<sup>127</sup> In an editorial describing the new guidelines, *Nature Genetics* discussed how the 2000 U.S. Census, in an effort to address the nation’s increasing diversity, includes an option for “Other Race” whereby individuals can self-select more than one ethno-racial category, opining that this change would “lead to 63 possible permutations.”<sup>128</sup> The editorial goes on to acknowledge that in most scientific communities, “race” is not a scientific term.<sup>129</sup> But then the *Journal* states that ethno-race can be a valid variable in scientific studies, a proxy for discriminatory experiences, diet or other environmental factors, but concludes that ethno-race should not be used as a substitute for measurable parameters such as genetic variation or differences in metabolism.<sup>130</sup>

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<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> *Id.* The *BMJ* editors also advise researchers to consider: “genetic differences . . . , self assigned ethnicity . . . , observer assigned ethnicity . . . , country or area of birth, years in country of residence, and religion.” *Id.* To determine genetic differences research should use “relevant genetically determined polymorphism”; nationally agreed guidelines would be used to determine “self-assigned ethnicity enabling comparability with census data”; observer assigned ethnicity would use “OPCS or other national census categorisation or the researchers’ own logically argued categories; and country or area of birth would be determined by using the subject’s own, or parents’ and grandparents’ if applicable.” *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> Editorial, *Census, Race and Science*, 24 *NATURE GENETICS* 97, 98 (2000).

<sup>128</sup> *Id.* at 97.

<sup>129</sup> *Id.* at 97-98. The editorial refers to the American Association of Anthropologists’ (AAA) 1997 recommendation that the U.S. government stop using race in collection of data because race is a social not a scientific concept. *Id.*

<sup>130</sup> *Id.* at 98. According to the *Journal*, the lack of discussion about the misuse of race is

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*Nature Genetics*'s goal in mandating journal guidelines is to “raise awareness and inspire more rigorous design of genetic and epidemiological studies.”<sup>131</sup> Thus it declared that, henceforth, the *Journal* will *require* authors to explain their use of specific ethno-racial groups and how that classification was achieved.<sup>132</sup> The hope is that these guidelines will encourage researchers to find ways to improve the health of populations without using ethno-race as a “pseudo-biological variable.”<sup>133</sup>

In 2001, the *New England Journal of Medicine (NEJM)* entertained a debate about the use of ethno-race in biomedical research, stopping short of imposing guidelines. Instead, it published a powerful editorial by Robert Schwartz, a deputy editor of the *NEJM*, criticizing the uncritical use of race in research.<sup>134</sup> He also encourages all journals to adopt the *Nature Genetics* guidelines on the use of racial and ethnic categories in medical research.<sup>135</sup>

In his editorial, Dr. Schwartz cites two articles published in the same issue that use race inappropriately.<sup>136</sup> Like others, he also believes that any study using ethno-racial categories “should begin with a plausible, clearly defined, and testable hypothesis” about the relevance of these categories.<sup>137</sup> A better approach, according to Schwartz, is to focus on genetic variations, rather than ethno-racial differences, reasoning that genetic similarities across ethno-race categories reported by the human genome project “should force an end to medical research that is arbitrarily based on race.”<sup>138</sup>

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a result of the sensitive and complex nature of the topic. *Id.*

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> Robert S. Schwartz, Editorial, *Racial Profiling in Medical Research*, 344 N. ENGL. J. MED. 1392 (2001).

<sup>135</sup> *Id.*

<sup>136</sup> The first article reports that carvedilol, a beta blocker, has a similar benefit in blacks and nonblacks with chronic heart failure. Clyde W. Yancy et al., *Race and the Response to Adrenergic Blockade with Carvedilol in Patients with Chronic Heart Failure*, 344 N. ENGL. J. MED. 1358 (2001). The second article compares the response of black and white patients to an angiotension-converting-enzyme inhibitor, enalapril. Derek V. Exner et al., *Lesser Response to Angiotensin-Converting-Enzyme Inhibitor Therapy in Black as Compared with White Patients with Left Ventricular Dysfunction*, 344 N. ENGL. J. MED. 1351 (2001). The researchers claim that an angiotensin-converting-enzyme inhibitor, enalapril, is more effective when used in whites with left ventricular dysfunction than blacks. *Id.* at 1351.

<sup>137</sup> Schwartz, *supra* note 134, at 1393.

<sup>138</sup> *Id.* See *supra* note 10, for more discussion of this point.

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Reflecting the ongoing debate about the use of race in biomedical research, Schwartz's editorial was countered by another editorial "praising" the use of race in medical research.<sup>139</sup> The debate in the *NEJM* continued in 2003 when the *Journal* published another pair of articles for and against the uncritical use of race in research.<sup>140</sup> Today the question of *NEJM* guidelines in this area remains unresolved.

Most of the journal guidelines are similar to the recommended guidelines announced in 2008 by a multi-disciplinary group from Stanford University (hereinafter the Stanford Group).<sup>141</sup> Although these guidelines regarding the use of ethno-racial categories were developed for use in research exploring "human genetic variation"<sup>142</sup>, they seem equally applicable to biomedical research. In some respects the *Nature Genetics* guidelines are almost identical to provisions of the Stanford Group guidelines. *Nature Genetics*, for example, requires authors to "explain why they make use of particular ethnic groups or populations, and how classification was achieved."<sup>143</sup> The Stanford Group encourages researchers to "describe how individual samples are assigned category labels, [and] to explain why samples with such labels were included in the study."<sup>144</sup> Unfortunately, however, the *Nature Genetics* guidelines, like the guidelines proposed by *JAMA* and *BMJ*, fail to address the myriad of other issues surrounding racial categorization presented in the Stanford Group model.

More specifically, the Stanford Group recommends that researchers, when considering whether to use ethno-race as a factor in a study, ask themselves three questions: (1) why race or ethnicity is relevant to the study, (2) how race or ethnicity is to be determined and

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<sup>139</sup> Lillquist & Sullivan, *supra* note 20, at 394 (citing Alastair J.J. Wood, *Racial Differences in the Response to Drugs—Pointers to Genetic Differences*, 344 *NEW ENG. J. MED.* 1393 (2001) (favoring the use of race)).

<sup>140</sup> *Id.* (citing Esteban González Burchard et al., *The Importance of Race and Ethnic Background in Biomedical Research and Clinical Practice*, 348 *NEW ENG. J. MED.* 1170 (2003) (favoring the use of race) and Richard S. Copper et al., *Race and Genomics*, 348 *NEW ENG. J. MED.* 1166 (2003) (opposing the use of race)).

<sup>141</sup> Lee et al., *supra* note 108, at 404. The *Journal* requires authors to "explain why they make use of particular ethnic groups or populations, and how classification was achieved." Editorial, *supra* note 127, at 98. The Stanford Group encourages researchers to "describe how individual samples are assigned category labels, [and] to explain why samples with such labels were included in the study." Lee et al., *supra*, at 404.2. The Stanford Group consists of "faculty from the humanities, social sciences, life sciences, law and medicine." *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> Editorial, *supra* note 127, at 98.

<sup>144</sup> Lee et al. *supra* note 108, at 404.2.

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(3) whether the ethno-racial categories are variables in the research.<sup>145</sup> Thus rather than construct a study of cancer rates among ethno-racial groups, they argue that it might be more appropriate to construct a study of cancer rates based on age or gender that also records the ethno-race of subjects. Only Schwartz, however, agrees with the Stanford Group about the importance of education in remedying the problem.<sup>146</sup> He writes that educating academics and researchers about “the fallacy of race as a scientific concept” is an especially important component in preventing misuse of race in medical research.<sup>147</sup>

The journal guidelines have had mixed results. *BMJ* published sixteen post-guideline studies between 2000 and 2009 with one of the following terms in the title: race, racial, ethnic, ethnicity.<sup>148</sup> Four studies

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<sup>145</sup> *Id.* The Stanford Group writes that in designing a research protocol that minimizes the “use of science for racial stereotyping. . . . Researchers can assess the purpose and impact of using racial and ethnic categories in their research and investigate whether alternative approaches would be appropriate.” *Id.* For another perspective on the use of race and ethnicity as research variables, see Dale E. Hammerschmidt, *It’s as Simple as Black and White! Race and Ethnicity as Categorical Variables*, 133 J. LABORATORY CLIN. MED. 10, 12 (1999) (suggesting that race should be treated the same as other categorical variables by identifying what about race may be important to the study [which often leads to a more appropriate socioeconomic variable] establishing criteria for subject assignment, and applying such criteria consistently, in an organized manner; emphasizing clarity in the method of subject assignment and awareness of the potential misuse of study findings.)

<sup>146</sup> Robert S. Schwartz, *Racial Profiling in Medical Research*, 344 N. ENGL. J. MED. 1392, 1393 (2001); Lee et al., *supra* note 108, at 404.3.

<sup>147</sup> Schwartz, *supra* note 146, at 1392; Lee et al., *supra* note 108, at 404.3 (arguing for the genetics curriculum to include a history of the use of science to further racist theories and policies).

<sup>148</sup> Imelda Balchin et al., *Racial Variation in the Association Between Gestational Age and Perinatal Mortality: Prospective Study*, 334 BRIT. MED. J. 833 (2007); J. Boydell et al., *Incidence of Schizophrenia in Ethnic Minorities in London: Ecological Study into Interactions with Environment*, 323 BRIT. MED. J. 1336 (2001); Annie Britton et al., *Does Access To Cardiac Investigation and Treatment Contribute to Social and Ethnic Differences in Coronary Heart Disease? Whitehall II Prospective Cohort Study*, 329 BRIT. MED. J. 2004; Francesco Cappuccio et al., *Application of Framingham Risk Estimates to Ethnic Minorities in United Kingdom and Implications for Primary Prevention of Heart Disease in General Practice: Cross Sectional Population Based Study*, 332 BRIT. MED. J. (2002); Desiree M.A. Choi et al., *Ethnicity and Prescription Analgesia in Accident and Emergency Departments*, 320 BRIT. MED. J. 513 (2000); Gene Feder et al., *Ethnic Differences in Invasive Management of Coronary Disease: Prospective Cohort Study of Patients Undergoing Angiography*, 324 BRIT. MED. J. 511 (2002); Nick Freemantle et al., *What Factors Predict Differences in Infant and Perinatal Mortality in Primary Care Trusts in England?*, 339 BRIT. MED. J. 2892 (2009); Julia Hippisley-Cox et al., *Association of Deprivation, Ethnicity, and Sex with Quality Indicators for Diabetes*, 329 BRIT. MED. J. 1267 (2004) [hereinafter Hippisley-Cox et al. I]; Julia Hippisley-Cox et al., *Predicting risk of Type 2 Diabetes in England and Wales: Prospective Derivation and Validation of Qdscore*, 338 BRIT. MED. J. b880 (2009) [hereinafter Hippisley-Cox et al. II]; Marian Knight et al., *Inequalities in Maternal*

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clearly meet the *BMJ* guidelines, if the census categories provide adequate description of the ethno-racial categories.<sup>149</sup> In the other studies, it is unclear whether the first guideline recommending the use of accurate ethno-racial descriptions is actually met. Some articles provide no description of the ethno-racial categories beyond the names of the categories themselves.<sup>150</sup> Thus, while we know what is included in the ethno-racial category (i.e., black includes black African, black Caribbean, and mixed), the categories in the studies still use the broad, non-descriptive terms (i.e., black, white, non-white, and Asian) that the guidelines hoped to discourage.

The most difficult part of the *BMJ* guidelines to discern is whether the ethno-racial categorization in these studies relates to the type of hypothesis under investigation. According to the guidelines, “race has little biological validity”; therefore, if the studies were looking for biological differences, they should have used categories based on genetic variation, not race. If the studies were merely looking for racial disparities in quality and access to health care, or the impact of social and

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*Health: National Cohort Study of Ethnic Variation in Severe Maternal Morbidities*, 338 BRIT. MED. J. b542 (2009); Trevor W Lambert et al., *Characteristics of Consultants Who Hold Distinction Awards in England and Wales: Database Analysis with Particular Reference to Sex and Ethnicity*, 328 BRIT. MED. J. 1347 (2004); Kath Moser et al., *Inequalities Reported in the Use of Breast and Cervical Screening in Great Britain*, 338 BRIT. MED. J. b2025 (2009); Sonia Saxena et al., *Socioeconomic and Ethnic Group Differences in Self Reported Health Status and Use of Health Services by Children and Young People in England: Cross Sectional Study*, 325 BRIT. MED. J. 520 (2002); Jane Wardle et al., *Development of Adiposity in Adolescence: Five Year Longitudinal Study of an Ethnically and Socioeconomically Diverse Sample of Young People in Britain*, 332 BRIT. MED. J. 1130 (2006); Peter H. Whincup et al., *Early Evidence of Ethnic Differences in Cardiovascular Risk: Cross Sectional Comparison of British South Asian and White Children*, 324 BRIT. MED. J. 635 (2002); Katherine Woolf et al., *Ethnic Stereotypes and the Underachievement of UK Medical Students from Ethnic Minorities: Qualitative Study*, 337 BRIT. MED. J. a1220 (2008).

<sup>149</sup> Hippisley-Cox et al. II, *supra* note 148; Knight et al., *supra* note 148; Saxena et al., *supra* note 148; Woolf et al., *supra* note 148. The census categories are as follows: white (includes options for British, Irish, or any other white background), mixed (includes options of White and Black Caribbean, White and Black African, White and Asian, or any other mixed background), Asian or Asian British (includes options for Indian, Pakistani, Bangladeshi, any other Asian background), Black or Black British (includes options for Caribbean, African, any other black background), Chinese or other ethnic group (includes options for Chinese, or write-in for other ethnic group). *Census 2001: Ethnicity and Religion in England and Wales*, U.K. NATIONAL STATISTICS: CENSUS 2001 (2003),

<http://www.statistics.gov.uk/census2001/profiles/commentaries/ethnicity.asp#background>  
<sup>150</sup> Balchin et al., *supra* note 148; Boydell et al., *supra* note 148; Britton et al., *supra* note 148; Cappuccio et al., *supra* note 148; Choi et al., *supra* note 148; Feder et al., *supra* note 148; Freemantle et al., *supra* note 148; Hippisley-Cox et al. I, *supra* note 148; Lambert et al., *supra* note 148; Moser et al., *supra* note 148; Wardle et al., *supra* note 148; Whincup et al., *supra* note 148.

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environmental factors on health outcomes, then ethno-racial categories may be appropriate. Several articles seemed to use race this way,<sup>151</sup> but a few articles seem to be looking for biological difference, and therefore used ethno-racial categories inappropriately.<sup>152</sup>

Looking at similar studies published in *Nature Genetics* from 2000 to 2009, only one of the four identified studies seems to meet the criteria established by that journal.<sup>153</sup> Two of the three remaining studies meet one of the two guidelines, but differ as to which guideline was met.<sup>154</sup> The last study does not seem to meet either guideline.<sup>155</sup> Thus, there is no real pattern as to how authors use or disregard the *Nature Genetics* guidelines.<sup>156</sup>

While the journal guideline statements are promising developments, without stringent oversight, there is little incentive for researchers to change their methodologies or thinking about ethno-race. Even mandatory guidelines, like those established by *Nature Genetics*, are not always enforced. The federal guidelines on ethno-racial categories are equally problematic, but for different reasons, a point explored in next section.

### B. Federal Guidelines on Ethno-race in Biomedical Research

Although life expectancy and overall health for all Americans improved substantially in the twentieth century, significant health

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<sup>151</sup> Hippisley-Cox et al. (I and II); Feder et al.; Moser et al.; Choi et al.; Lambert et al.; Knight et al.; Freemantle et al.; Saxena et al.; Boydell et al.; Britton et al.; Woolf et al.

<sup>152</sup> These studies seem to use ethno-race inappropriately: Whincup et al.; Cappuccio et al. It is unclear whether the following studies use race inappropriately: Balchin et al., Wardle et al.

<sup>153</sup> The *Nature Genetics* article that meets both guidelines is John P.A. Ioannidis et al., 'Racial' Differences in Genetic Effects for Complex Diseases, 36 NATURE GENETICS 1312 (2004).

<sup>154</sup> The *Nature Genetics* articles that meet one of the two guidelines are Anna Helgadottir et al., A Variant of the Gene Encoding Leukotriene A4 Hydrolase Confers Ethnicity-Specific Risk of Myocardial Infarction, 38 NATURE GENETICS 68 (2006), and Richard S. Spielman et al., Common Genetic Variants Account for Differences in Gene Expression Among Ethnic Groups, 39 NATURE GENETICS 226 (2007).

<sup>155</sup> The *Nature Genetics* article that met neither guideline is E.J. Parra et al., Implications of Correlations Between Skin Color and Genetic Ancestry for Biomedical Research, 36 NATURE GENETICS S54 (2004).

<sup>156</sup> Although the journal guidelines are intended for clinical studies, two commentaries published in *Nature Genetics* seem to partially meet the guidelines. The two *Nature Genetics* commentaries are: Hua Tang, Confronting Ethnicity-Specific Disease Risk, 38 NATURE GENETICS 13 (2006); David B. Goldstein & Joel N. Hirschhorn, In Genetic Control of Disease, Does 'Race' Matter?, 36 NATURE GENETICS 1243 (2004).

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disparities remained, especially among racial and ethnic minority communities.<sup>157</sup> As a result, in 1998 President Clinton proposed a twelve year plan to end health disparities in six areas.<sup>158</sup> The Clinton effort was one of many national attempts to address health disparities among Americans.<sup>159</sup> Today the National Institute on Minority Health and Health Disparities (NIMHD) leads, coordinates, supports and assesses the NIH research effort to reduce and ultimately eliminate health disparities as they affect racial and ethnic communities and medically underserved individuals.<sup>160</sup>

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<sup>157</sup> David Satcher, *Our Commitment to Eliminate Racial and Ethnic Health Disparities*, 1 YALE J. HEALTH POL'Y & ETHNICS 1, 1 (2001).

<sup>158</sup> *Id.* at 2. The six areas are: cancer screening and management, cardiovascular disease, diabetes, HIV/AIDS, immunization rates, and infant mortality.

<sup>159</sup> “Clinton’s goal parallel[ed] the focus of Healthy People 2010—the nation’s health objectives for the twenty-first century—which Donna Shalala, former Secretary of the Department of Health and Human Services (DHHS), . . . released in January 2000.” *Id.* In 1986, the Office of Minority Health (OMH) was created as a component of the U.S. Department of Health and Human Services (HHS) to “advise[] the Secretary and the Office of Public Health and Science (OPHS) on public health program activities affecting American Indians and Alaska Natives, Asian Americans, Blacks/African Americans, Hispanics/Latinos, Native Hawaiians, and other Pacific Islanders.” *About the Office of Minority Health*, U.S. DEP’T OF HEALTH AND HUM. SERVS., <http://www.omhrc.gov/templates/browse.aspx?lvl=1&lvlID=7> (last visited Dec. 17, 2010); 50 Fed. Reg. 50,847 (Dec. 12, 1985) (creating the OMH). In 1990 the National Institutes of Health (NIH) created an Office of Minority Health (OMH) to “promote research and training related to the disproportionate incidence of disease among members of racial and ethnic minority groups.” Phyllis Griffin Epps, *The Health Care Fairness Act of 1999*, U. HOUSTON HEALTH LAW & POL’Y CTR. (Nov. 18, 1999), <http://www.law.uh.edu/Healthlaw/perspectives/HealthPolicy/991118HCFAct.html>; see also Jeffrey Brainard, *Debate Over Improving Minority Health Pits NIH Director Against Black Leaders*, CHRON. HIGHER EDUC., Sept. 10, 1999, at A41. In 1992 (ORMH) unveiled the *Minority Health Initiative* (MHI), consisting of a multi-year biomedical and behavioral research and research training program designed to “improve prenatal health and reduce infant mortality”; fund “studies of childhood and adolescent lead poisoning, HIV infection and AIDS; and alcohol and drug use”; “research in adult populations focused on cancer, diabetes, obesity, hypertension, cardiovascular diseases, mental disorders, asthma, visual impairments, and alcohol abuse”; and train “faculty and for students at all stages of the educational pipeline.” *The NIH Almanac*, NAT’L INST. OF HEALTH, <http://www.nih.gov/about/almanac/organization/NIMHD.htm> (last visited Dec. 17, 2010); Press Release, National Institutes of Health, Office of Minority Health and Research (Apr. 14, 2000), <http://www.nih.gov/news/pr/apr2000/od-14.htm>

<sup>160</sup> The Institute was until recently the National Center for Minority Health and Health Disparities. See Press Release, NIH, NIH Announces Institute on Minority Health and Health Disparities (Sept. 27, 2010), <http://www.nih.gov/news/health/sep2010/nimhd-27.htm>. The National Institutes of Health (NIH) has several programs engaged in “medical research concerning racial and ethnic minorities. Sample research programs at the NIH include: [the] National Institute on Minority Health and Health Disparities (NIMHD): [that] . . . leads, coordinates, supports and assesses the NIH research effort to reduce and ultimately eliminate health disparities as they affect racial and ethnic communities and medically underserved individuals. . . . Centers for Population Health and Health Disparities. . . . designed to support research to understand and reduce



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These well-intended legislative attempts to encourage greater study of minority health send confusing signals to researchers. As Dorothy Roberts points out, the federal funding guidelines create a paradox: guideline measures designed to remedy past discrimination and exclusion in biomedical research based on ethno-racial labels actually require race consciousness. This form of race-consciousness, however, risks “reinforcing biological definitions of race that have historically legitimized racial inequalities.”<sup>161</sup> Thus, then-U.S. Surgeon General Dr. David Satcher, a black physician, had to remind readers in the supplement to a comprehensive 1999 federal report on mental health that the term race as used in that report referred to “social characteristics held in common, such as general societal treatment and access to resources,” and not purported biological differences.<sup>162</sup>

Federal grant application regulations establish guidelines and provide incentives for the inclusion of different racial and ethnic groups in clinical trials.<sup>163</sup> But these guidelines also create confusion. Section 5.8 of the Application Guide for NIH and Other Public Health Services (PHS) Agencies, for example, explains the inclusion guidelines for federally funded studies.<sup>164</sup> Under this provision, studies funded by these

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differences in health outcomes, access and care. ... NIH’s National Health Lung and Blood Institute (NHLBI) partners with African American communities through Enhanced Dissemination and Utilization Centers to implement education and intervention programs to cut the rates of CVD risk factors and to promote healthy lifestyles. NHLBI is also conducting the Jackson Heart Study C the first large-scale cardiovascular disease study among African Americans to examine the factors that influence the diseases development in this population. For more information ... [National] Institute of Environmental Health Sciences (NIEHS) ... [which is] a leader in the area of understanding how poverty, environmental pollution, and health interrelate.” Press Release, U.S. Dep’t of Health & Hum. Servs., Protecting the Health of Minority Communities (Jan. 13, 2006), <http://www.hhs.gov/news/factsheet/minorityhealth.html>. For further information on these and other environmental health programs of the NIEHS, visit <http://www.niehs.nih.gov/>. See also Nat’l Inst. on Minority Health, <http://www.nimhd.nih.gov/>.

<sup>161</sup> Roberts, *supra* note 11, at 528.

<sup>162</sup> Matt Boucher, *Turning a Blind (White) Eye in Legislating Mental Health Parity: The Unmet, Overlooked Needs of the Working Poor in Racial and Ethnic Minority Communities*, 19 J. CONTEMP. HEALTH L. & POL’Y 465, 466 n.5 (2003). Satcher defined ethnicity as “a common heritage shared by a particular group.” *Id.* (citing U.S. DEP’T OF HEALTH & HUMAN SERVS., MENTAL HEALTH: CULTURE, RACE, AND ETHNICITY: A SUPPLEMENT TO MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 9 (2001) [hereinafter MHCRE]). This report “uses the term ‘minority’ to ‘signify [a] group[’s] limited political power and social resources, as well as their unequal access to opportunities, social rewards, and social status.” *Id.* at 471 n.31 (citing MHCRE, *supra*, at 5).

<sup>163</sup> Jonathan Kahn, *Genes, Race, and Population*, 96 AM. J. PUB. HEALTH 1965, 1966 (2006).

<sup>164</sup> See U.S. DEP’T OF HEALTH & HUM. SERVS., PUBLIC HEALTH SERVICE GRANT APPLICATION INSTRUCTIONS § 5.8 (June 2009), available at

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federal agencies are required to “identify research subjects by race and ethnicity, to include minorities in clinical trials, and . . . report their findings according to the racial and ethnic identity of research subjects”<sup>165</sup> using OMB’s conceded socially constructed standards, which contain five racial and two ethnic categories.<sup>166</sup>

These guidelines seem to ignore OMB’s own caveat that “the racial and ethnic categories set forth in the standards should not be interpreted as being primarily biological or genetic in reference.”<sup>167</sup> Moreover, federal databases confuse racial and ethnic categories in genetic research because samples are organized into categories that overlap and/or conflate notions of race, ethnicity, nationality, continental geography, and religion.<sup>168</sup> Mindful that OMB’s categories are overly broad, NIH encourages reporting on ethno-racial categories in greater detail.<sup>169</sup> In determining ethno-race, NIH also advises researchers to use subject self-identification,<sup>170</sup> which as I previously argued is problematic.<sup>171</sup>

In addition to the inadequate descriptive racial categories, NIH’s enforcement mechanisms are not particularly helpful because they focus on problems that arise after the research project has received funding.<sup>172</sup> Continuation of the grant and disbursement of the award depend on the submission of periodic reports that must disclose the race and ethnicity

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<http://grants.nih.gov/grants/funding/phs398/phs398.pdf>.

<sup>165</sup> Roberts, *supra* note 11, at 529. She also argues that state laws are another potential regulatory site. *Id.* at 530.

<sup>166</sup> For a critique of the Office of Management and Budget’s (OMB) standards for reporting race and ethnic statistics, see *Response to OMB Directive 15*, *supra* note 64.

<sup>167</sup> Kahn, *Genes, Race, and Population*, *supra* note 163, at 1968.

<sup>168</sup> *Id.* at 1966-67.

<sup>169</sup> U.S. DEP’T OF HEALTH & HUM. SERVS., GRANT APPLICATION INSTRUCTIONS, *supra* note 164, at II-20 (“Subpopulations: Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study.”).

<sup>170</sup> *Id.* The OMB also encourages self-report: “respondent self-identification should be facilitated to the greatest extent possible, recognizing that in some data collection systems observer identification is more practical.”

<http://www.whitehouse.gov/omb/rewrite/fedreg/ombdir15.html>.

<sup>171</sup> See *supra* notes 72, 108-109, and accompanying text.

<sup>172</sup> “NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget periods.” See NIH GRANTS POLICY STATEMENT (2003), [http://grants1.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part5.htm#\\_Toc54600106](http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600106).

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of human subjects.<sup>173</sup> This system of oversight seems to give the NIH the ability to impose funding restrictions on studies that are not following the inclusion guidelines as mandated by federal law.

But the inappropriate use of ethno-race usually appears at the grant application stage in the research protocol. Further, the follow-up to determine whether researchers complied with their plan is not with the researchers, but with the institutes reviewing the proposals, who are required to prepare reports “describing the manner in which the institute has complied” with the Act.<sup>174</sup> While the NIH *Policy on Reporting Race and Ethnicity Data* suggests that researchers have to complete annual reports of the total enrollment by race, ethnicity, and gender, it does not address the consequences if researchers fail to comply with this requirement or identify race inappropriately.<sup>175</sup>

A 2006 study of adherence to federal guidelines for reporting race, ethnicity, and sex in federally funded clinical trials published in high impact journals in 2004 found that 67% of the trials reported the number of black subjects and 48% reported the number of Hispanic subjects, but 18% of studies reported nothing with respect to the race/ethnicity of their subjects.<sup>176</sup> These studies generally did not report results by race (which seems appropriate), and the vast majority did not acknowledge any limitations on generalizability due to the race or ethnicity of the subjects.<sup>177</sup> Further, none of the four phase III trials provided race-specific results or addressed any statistically significant racial/ethnic differences.<sup>178</sup> Despite the lack of compliance with the guidelines, and resulting lack of diversity among trial subjects, the vast majority of studies generalized the results to all populations.<sup>179</sup> Thus requiring researchers to be race conscious in the selection of clinical subjects does not necessarily translate into a reification of race in most

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<sup>173</sup> See *Final Progress Report*, NIH GRANTS POLICY STATEMENT (2003), [http://grants1.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part8.htm#\\_Toc54600141](http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600141).

<sup>174</sup> See NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14,508, 14,510 (Mar. 28, 1994).

<sup>175</sup> NIH Policy on Reporting Race and Ethnicity Data (Aug. 8, 2001), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>

<sup>176</sup> Geller et al., *supra* note 102, at 1126. The authors excluded studies that identified no federal support. In evaluating the articles, researchers noted whether race/ethnicity specific results were reported, whether race/ethnicity was considered in analyzing the outcomes, and whether the trials recognized any limitations on generalizability to broader populations based on race or ethnicity. Follow up papers were also examined for any information relating to race or ethnicity. *Id.* at 1124-25.

<sup>177</sup> *Id.* at 1127.

<sup>178</sup> *Id.* at 1128. The sex-specific OB-GYN studies similarly did not report results by race or ethnicity. *Id.* at 1127.

<sup>179</sup> *Id.* at 1130.

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federally funded studies.

Another study looked at the use of racial and ethnic terminology in genetic research, and whether the use of such terms is justified or explained when the research is published.<sup>180</sup> The researchers' concern was that using ethno-racial terms without providing definitions allows the reader to infer definitions that may be based on negative stereotypes, that in the context of genetic research, reinforce biological notions of race.<sup>181</sup> The results indicated that race or ethnicity terminology was used as a variable in a little more than half (51.5%) of the 330 articles.<sup>182</sup> Of the remaining articles, approximately half did not include race or ethnicity terms at all, while the other half used racial or ethnic terminology, but only to identify the study sample, not as a variable.<sup>183</sup>

Most articles neither explained nor justified the use of the populations studied.<sup>184</sup> Significantly, only 9.1% of articles explained how a label was given to a particular population, a basic procedure in some journal guidelines, and arguably “a basic, easily fulfilled requirement.”<sup>185</sup> The authors note that the failure to adequately explain the basis for ethno-racial assignment “impedes constructive use of study findings.”<sup>186</sup> But as recent studies of race-related stress discussed earlier illustrate, a more thoughtful use of ethno-race as descriptor and ascriptor can lead researchers to look more critically at these categories. Nevertheless, researchers still need effective guidelines about the use of ethno-race in biomedical research that are imposed at the beginning of the process.

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<sup>180</sup> Pamela Sankar et al., *Race and Ethnicity in Genetic Research* 143A AM. J. MED. GENETICS 961 (2007). The articles examined in this study show that the issue of ensuring clarity and precision in the use of racial and ethnic terminology still warrants attention, and “inadequate explanation of the meaning and purpose of race and ethnicity is widespread across journals.” *Id.* at 968.

<sup>181</sup> *Id.* at 962.

<sup>182</sup> *Id.* at 966.

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* at 968. Unlike the NIH guidelines, the FDA guidelines do “not address the level of participation of racial and ethnic groups in clinical trials” nor “establish legally enforceable responsibilities.” U.S. DEP’T OF HEALTH & HUM. SERVS., GUIDANCE FOR INDUSTRY: COLLECTION OF RACE AND ETHNICITY DATA IN CLINICAL TRIALS 2 (2005), available at

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf>.

Rather, the FDA guidelines on the collection of race and ethnicity data are actually a series of recommendations to help applicants meet the requirements of new drug applications that require subjects to be reported by race, among other factors. Logically then, the consequence of failing to follow FDA guidelines, or at least failing to collect racial and ethnic data, would be the inability to complete a new drug application process.

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The next section of this article offers a tentative standard applicable to concerns about ethno-racial inclusion in clinical studies, access to health care, and discrimination in treatment, as well as ethno-race related disease. A single regulatory scheme in federal minority health initiatives would minimize researcher confusion and trigger re-education about the use of ethno-race in biomedical research.

### **IV. Proposal for Regulating Biomedical Research Using Race/Ethnicity**

As my friend's bone density test story illustrates, racial identity is ambiguous, even in biomedicine. This section first proposes a two-step regulatory scheme that addresses the concerns raised in this article about the inappropriate use of ethno-race in biomedical research. Then this proposal is applied to a hypothetical race-related biomedical research proposal.

#### **A. A Proposed Regulatory Scheme**

One suggestion Dorothy Roberts makes about using funding restrictions to regulate the use of ethno-race in biomedical research is that researchers ask themselves questions like whether race is being defined biologically or socially; and whether membership in the racialized group “continue[s] to affect health status, access to care and medical treatment [] requiring race-conscious scientific investigation and legal remedies.”<sup>187</sup> While the focus of these questions is sound, there is too little guidance for reviewers and researchers.

The three questions recommended by the Stanford Group are sharper, and better suited for incorporation into NIH and other PHS funding guidelines. As mentioned previously, the Group advises researchers when considering ethno-racial categories to ask themselves first why race or ethnicity is relevant to the study and whether alternative approaches are more appropriate. Addressing this question helps them focus on the real objective of their study: whether there are differences in bone metabolism based on lifestyle.

Ethno-racial categories, for example, may be perfectly acceptable if researchers are assessing health services, but even in that situation, given the varied circumstances of black, Latino and Asian American subgroups, broad non-descriptive terms like black, white, non-

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<sup>187</sup> Roberts, *supra* note 11, at 531.

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white and Asian should be avoided. On the other hand, ethno-racial categories may be totally inappropriate if studying the correlation between diet and high blood pressure. Other factors like socio-economic status, geographical location, gender, and family medical history may be more accurate and helpful.

A second question is how race or ethnicity will be determined. As my foregoing discussion points out, subject self-identification as opposed to researcher identification may be appropriate if studying access to health care or physician bias, but unhelpful when studying the prevalence of certain diseases or conditions like sickle cell that are more prevalent in certain areas of the world. In that case, looking at subjects' bio-geographic ancestry might provide a more useful measure.

The third question is whether the ethno-racial categories are variables in the research.<sup>188</sup> Given that ethno-race has little if any biological basis, researchers should avoid research protocols that use only ethno-racial categories. Thus, ethno-race should not be used as a variable outside of access to health care and treatment.

These three questions should be threshold inquiries that applicants must address in their request for federal funding. High impact journals also should ask these same questions when researchers submit their findings for publication. Thus there would be a check at both ends of the process with funding and publication tied to compliance with these guidelines.

Not only should federal funding guidelines on the use of race in biomedical research be clear and precise, they also should be mandatory. But, as the experience with the *Nature Genetics* publishing guidelines indicates, mandatory guidelines seem no more effective than aspirational ones. Thus additional checks are needed.

When a grant applicant's answers to any of the three threshold questions raise the possibility that ethno-race will be used as an ascriptive factor, an additional inquiry would be triggered. In that instance a multi-disciplinary health impact assessment group (HIAG) would be convened.<sup>189</sup> This group would be charged with drafting a

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<sup>188</sup> Lee et al., *supra* note 108, at 404.2.

<sup>189</sup> Information about health impact assessments (HIAs) can be found on the World Health Organization website. *Health Impact Assessments*, WORLD HEALTH ORG., <http://www.who.int/hia/en/> (last visited Dec. 17, 2010); *see also* R. Quigley et al., *Health Impact Assessment: International Best Principles*, INT'L ASS'N FOR IMPACT ASSESSMENT (2006), <http://www.iaia.org/publicdocuments/special-publications/SP5.pdf> (summarizing

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health impact assessment (HIA) to “clarify the expected health implications of a given action, and of any alternatives being considered, for the population groups affected by the proposal.”<sup>190</sup>

The determinants of health include individual factors, social, environmental, and institutional factors.<sup>191</sup> A HIA is a valuable tool to protect against the misuse of race in scientific research because it is designed “to clarify health implications by disaggregating the determinants of health and well-being.”<sup>192</sup> In addition, a HIA focuses on informed decision-making, and as such, “attempts to identify health inequalities that may arise from a proposal.”<sup>193</sup>

Legal scholar Osagie K. Obasogie proposed a similar impact assessment mechanism he calls a racial impact assessment, as a regulatory tool to prevent new biotechnologies from advancing unsubstantiated notions of biological race.<sup>194</sup> Although he uses the FDA approval process as an example of when race impact assessments would be appropriate, he notes that this process may be useful in other contexts.<sup>195</sup> The value of race impact assessments, according to Obasogie, is the shared responsibility between “regulators, researchers, internal review boards, and affected communities and their

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health impact assessments).

<sup>190</sup> N. Krieger et al., *Assessing Health Impact Assessment: Multidisciplinary and International Perspectives*, 57 J. EPIDEMIOLOGY & CMTY. HEALTH 659, 660 (2003) (citing the World Health Organization).

<sup>191</sup> INT’L FINANCE CORP., WORLD BANK GROUP, INTRODUCTION TO HEALTH IMPACT ASSESSMENT 7 (2009), available at [http://www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/p\\_HealthImpactAssessment/\\$FILE/HealthImpact.pdf](http://www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/p_HealthImpactAssessment/$FILE/HealthImpact.pdf).

<sup>192</sup> Quigley et al., *supra* note 190, at 2.

<sup>193</sup> *Id.* The World Health Organization identifies several guiding principles of HIAs, including equity, defined as “emphasizing the desire to reduce inequality that results from avoidable differences in the health determinants and/or health status within and between different population groups.” *Id.* at 3. Another guiding principle, the ethical use of evidence, focuses on ensuring that “the best available evidence from different disciplines and methodologies is utilized, that all evidence is valued, and that recommendations are developed impartially.” *Id.*

<sup>194</sup> Obasogie, *supra* note 19, at 496. As an example, Obasogie proposes an FDA advisory committee “as part of its review process to evaluate whether medicines like BiDil might reinforce biological understandings of race when no biological or genetic mechanism has been identified. OBASOGIE, GENE CARD, *supra* note 16, at 47. Obasogie’s recommendation is equally workable for biomedical research. The ultimate goal in both instances is to “increase the dialogue between stakeholders and policymakers so as to balance competing interests through strategic planning that promotes public good.” *Id.*

<sup>195</sup> He also suggests race impact assessments in evaluating marketing of ancestry tests and the effects of DNA forensics on certain communities. OBASOGIE, GENE CARD, *supra* note 16, at 47.

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representatives.”<sup>196</sup> My proposal expands on Obasogie’s idea, applying it to biomedical research in general and providing a more detailed example below of how the assessment impact would work.

### **B. Applying the Proposed Standard: Bone Density Studies Revisited**

This section explains how the two-step process I outlined in the prior section might work in real life. Suppose researchers submitted a grant proposal seeking federal funding for a study examining whether racial differences in bone density between blacks and whites can be explained by differences in bone metabolism and lifestyle.<sup>197</sup> The researchers propose to study a cohort of roughly equal numbers of women and men, black and white, between the ages of 25-36 years.<sup>198</sup>

Other than reporting ethno-race to comply with federal regulations designed to ensure greater access to clinical trials by ethno-racial minorities, other use of ethno-race automatically would be suspect.<sup>199</sup> If ethno-racial categories are to be used for other purposes, researchers must explain why these categories are relevant. Thus the researchers in my hypothetical would need to explain why race is relevant in their study. They might justify the use of ethno-racial categories to examine the validity of earlier studies that found differences in bone density between whites and blacks saying that they are trying to determine whether these differences reflect lifestyle rather than racial differences.

As my foregoing discussion indicates this justification suggests that race would be used ascriptively and thus inappropriately. Thus the

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<sup>196</sup> *Id.* at 46.

<sup>197</sup> See Bruce Ettinger et al., *Racial Differences in Bone Density Between Young Adult Black and White Subjects Persist after Adjustment for Anthropometric, Lifestyle, and Biochemical Differences*, 82 J. CLIN. ENDOCRINOLOGY & METABOLISM 429 (1997). This study was supported in part by the National Institute of Health & Human Services. *Id.* The researchers conclude that “the appearance of . . . large racial difference in young adults cannot be attributed to persistent differences in metabolic or lifestyle factors and supports the view that bone density differences result from influences operating during childhood and adolescence.” *Id.* at 434.

<sup>198</sup> *Id.* at 430. The researchers also excluded “for certain laboratory abnormalities and pregnancy-related criteria. . . . breast-feeding women” and women currently using oral contraceptives. *Id.*

<sup>199</sup> As mentioned previously, federal regulations require that researchers use a universal standard, the OMB ethno-racial categories, in reporting the diversity of the research study subject population. The use of OMB ethno-racial categories is under the regulations as a way of guarding against past exclusionary practices, but these categories are insufficiently precise for biomedical purposes, even in access to health care studies. Braun et al., *supra* note 9, at 1425.



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second step of my proposal, an HIA, might be triggered at this stage. HIAG members might discuss whether the proposed use of ethno-race in the study tends to reinforce biological understandings of race when no biological or genetic mechanism has been identified. If so, the HIAG members might require that the researchers reconsider the proposed use of ethno-race or they will withhold funding until the researchers modify their protocol so that ethno-racial categories are eliminated or used appropriately.

Assuming the researchers can satisfactorily explain the relevance of race in their proposed study, the next inquiry is how the race of subjects would be determined for biomedical research as opposed to federal reporting purposes. Consider again the problem with determining the racial classification of the clinical subject mentioned earlier who self-identifies as Cape Verdean. This is a question Braun and her co-authors address.<sup>200</sup> Their response is that this individual defies conventional census-related racial classification for biomedical purposes.<sup>201</sup> If researchers' proposed method for identifying the race of clinical subjects in this case seems inappropriate, an HIA could be triggered at this point.

HIAG members might suggest other approaches. One possible approach in determining the ethno-race of a clinical subject might be to supplement the detailed subject self-identification collected for reporting purposes with a questionnaire to ascertain a subject's bio-geographical ancestry. Thus if my friend, for example, was a subject, she might self-identify as black or African American (as opposed to black Caribbean or black South African or Afro-Cuban or bi/multi-racial). The supplemental questionnaire would ask more detailed information about bio-geographic ancestry, where she was raised and currently resides.

This additional information helps separate recent immigrants from native-born Americans, perhaps an important variable in some studies and naturally leads to an examination of the answer to the third question, whether ethno-race as a variable in the research. Under the Stanford Group standard ethno-race should not be used as a variable outside of studies of access to health care and treatment. Thus if the research protocol indicates that research would be used in another context, this would trigger an HIA.

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<sup>200</sup> *Id.*

<sup>201</sup> "In clinical research projects or in the clinic, the assignment of race assumes an equivalence between census categories and genetics embodied by patients. . . . We suggest that, as with Cape Verdeans, census race cannot be assumed to reflect a particular genetic make-up." *Id.*

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Concededly an HIA inquiry can be a costly and labor intensive mechanism to protect against the inappropriate use of ethno-race in biomedical research. But without rigorous guidelines like the ones I propose, researchers will continue “to use these same variables in the subsequent analysis and theoretical framing of the research.”<sup>202</sup> Hopefully, HIA inquiries will be temporary measures that can be useful in helping federal funding agencies develop more substantial guidelines as they gain more experience reviewing individual protocols.

But better federal guidelines alone will be insufficient to remedy the problem I have described. My suggestions are just a first step in changing the way the medical community thinks about ethno-race. The importance of better biology education, starting in high school, also is essential in addressing the tendency to misuse ethno-race in biomedical research.<sup>203</sup> But changing how medical research communities think about race will be difficult. Researchers, many of whom are affiliated with medical schools, continue to use outdated and inaccurate notions about the validity of racial and ethnic differences in medical research unrelated to healthcare access and provider treatment bias. These researchers transmit their biases to their students replicating the problematic use of ethno-race in medical research and practice.

### V. Conclusion

As my friend’s experience with her bone density test illustrates, health care providers, like biomedical researchers, continue to rely, often unthinkingly, on socially constructed racial categories in treatment and diagnosis, often to the detriment of ethnic and racial minorities.<sup>204</sup> I know this from personal experience. In 1983 my daughter’s pediatrician suspected she had Crohn’s Disease and required hospitalization. But upon her admission to Texas Children’s Hospital in Houston the pediatric gastroenterologist, one of the best in the nation, resisted this diagnosis, telling me that Crohn’s Disease was found in “middle-class Jewish children”, not black children. It took ten days of testing before

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<sup>202</sup> Braun et al., *supra* note 9, at 1425.

<sup>203</sup> Braun and her co-authors write: “Improved medical training about race can sharpen diagnostic skills. Cultural competency instruction should be modified to include information on the history of racial categories, current controversies about their biological significance, and the limits of their utility. A teaching unit on race would also contrast the differences between race as a population concept with its meaning when applied to the lives of individuals. In this context it would be appropriate to teach about geographical variations in specific allele frequencies for genes linked to particular disease processes, as well as the cultural practices, historical trends, and environmental conditions that favor their prevalence or not.” Braun et al., *supra* note 9, at 1427.

<sup>204</sup> Roberts, *supra* note 11, at 531.

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the gastroenterologist agreed with the pediatrician's initial diagnosis.

It is important to determine the validity of ethno-racial classifications in each setting. In medicine, as in other areas, ethno-race is so powerful that it tends to shout, drowning out other explanations for adverse health outcomes. As Troy Duster explains “[t]he task is to determine how the social meaning of race can affect biological outcomes.”<sup>205</sup> Funding guidelines that force researchers to think more critically about any proposed use of ethno-race in biomedical research is one important mechanism government can use to discourage the inappropriate use of ethno-racial categories in biomedical research and ultimately the medical treatment of all Americans.

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<sup>205</sup> Troy Duster, *Buried Alive: The Concept of Race in Science*, CHRON. HIGHER EDUC., Sept. 14, 2001 at B12. See also Pilar Ossorio & Troy Duster, *Race and Genetics: Controversies in Biomedical, Behavioral, and Forensic Sciences*, 60 AM. PSYCHOLOGIST 115, 116 (2005).