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# Involuntary Consent: Conditioning Access to Health Care on Participation in Clinical Trials

*Ruqaiijah A. Yearby*

“Governments exist to protect the rights of minorities. The loved and the rich need no protection: they have many friends and few enemies.”

— Wendell Phillips

“Vulnerability manifests an asymmetrical imbalance between the weak and the powerful and in this context [bioethics] it demands an ethical engagement and that the powerful protect the weak.”

— Jacob Rendtorff

## **I. Background**

Although the controversy over the lack of consent in fetal-tissue clinical trials is relatively new, history is replete with instances of medical researchers who have conducted clinical trials with minorities and the economically disadvantaged without their consent.<sup>1</sup> Traditionally, American bioethics has served as a safety net for the rich and powerful (for they are not forced to act as research subjects to obtain access to health care for themselves or their children) while failing to protect the vulnerable, which includes minorities and the economically disadvantaged. Without access to health care, minorities and the economically disadvantaged are unduly influenced to participate in clinical trials that promise access to health care.

For example, researchers at Johns Hopkins University hospital unduly influenced economically disadvantaged Baltimore parents into enrolling their children into a research study to prove criminality by lying about the purpose of the study and promising them access to free health care otherwise denied by Hopkins.<sup>2</sup> The researchers enrolled more than 7,000 boys, 95% of who came from poor African American families, into a study to determine whether having an extra “Y” chromosome increased criminality, but they told the parents that the study was to test for anemia and other medical problems. The study did not show a positive association between the extra “Y” chromosome and criminality or violence in the boys studied, yet the blood samples linked to names were given to the police.<sup>3</sup> The researchers not only failed to get consent from the parents because they lied about the purpose of the research, but they also unduly influenced the parents into participating in the study by offering them access to health care that was usually withheld,

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and both actions were a violation of the bioethical principle of “respect for persons.”

The “respect for persons” principle requires that “individuals be treated as autonomous agents” by obtaining their informed consent before they participate in clinical trials.<sup>4</sup> In order for the consent to be valid, it must be free of undue influence, which includes inducements such as promises of access to health care. Promises of access to health care invalidate the voluntariness of consent because it leaves potential research subjects without choice, especially when the very institutions that are denying minorities and the economically disadvantaged access to health

**In this paper, I will discuss how race and class biases are central to the bioethical debate about informed consent, why these biases prevent access to health care, and thus, must be addressed to ensure that research subjects are not being unduly influenced into participating in clinical trials to attain access to health care.**

care are conducting the clinical trial. Without any meaningful choice to access health care other than participation in clinical trials, minorities and the economically disadvantaged are induced into consenting.

Thus, according to Professor Patricia King, instead of serving as a means of protection, bioethical principles, such as “respect for persons,” are used to promote “scientific and medical advances without recognizing that these developments occur in a social context that must be taken into account if the ethical issues are to be adequately addressed.”<sup>5</sup> Specifically, when applying the “respect for persons” principle, researchers and regulators often fail to take into consideration the class and racial biases that prevent minorities and the economically disadvantaged from attaining equal access to economic opportunities. Without equal access to these opportunities, minorities and the economically disadvantaged are prevented from accessing health care because of structural and institutional biases within the health care system.

As a result of structural bias, health care services in the United States are delivered based on ability to pay, leaving those who cannot pay (predominately minorities and the economically disadvantaged) without access to health care. Institutional biases result in the

accumulation of health care facilities and physicians in wealthy, Caucasian neighborhoods that do not accept government health insurance, such as Medicare and Medicaid,<sup>6</sup> and lawsuits for payment by hospitals, leaving those who are a minority and economically disadvantaged with little to no access to health care. Burdened by disease and denied care from health care institutions, even in emergency situations, minorities and the economically disadvantaged are induced into participating in clinical trials to gain access to health care.

In this paper, I will discuss how race and class biases are central to the bioethical debate about informed consent, why these biases prevent access to health care, and thus, must be addressed to ensure that research subjects are not being unduly influenced into participating in clinical trials to attain access to health care. To measure whether consent is voluntary, federal agencies such as the U.S. Department of Health and Human Services (HHS) should require researchers to use the Vulnerability and Equity Impact Assessment tool, which I have created based on the Health Equity Impact Assessment tool, to determine whether minorities and the economically disadvantaged are being unduly influenced into participating in clinical trials in violation of the “respect for persons” principle.

## **II. Respect for Persons: Voluntary Informed Consent Required**

Created with the drafting of the Belmont Report in 1979, current American bioethical principles are supposed to protect the rights and health of research subjects while participating in clinical trials.<sup>7</sup> One of the main bioethical principles in the Belmont Report, the “respect for persons” principle requires research subjects to be informed about the potential risks and burdens of participating in clinical trials before consenting to participation. This principle was created in response to abuses of the economically disadvantaged, minorities, children, and prisoners. One of the main impetuses for the creation of protections for the economically disadvantaged and minorities participating in clinical trials was the Tuskegee Syphilis Study.

From 1932 until 1972, researchers enrolled economically disadvantaged African American men who lacked access to health care in a clinical trial to document the course of syphilis, even though the course of the disease was already known. In exchange for free meals, access to health care, and burial insurance, the

researchers promised the men that they would provide treatment for their “bad blood,” a nebulous complaint that could include “anemic blood to muscle aches, general malaise, disorders such as parasitic infections, gonorrhea, syphilis, and other venereal disease.”<sup>8</sup> The researchers never informed the men that they were participating in a clinical trial, and therefore, never told them about the purpose of the trial. Researchers also intentionally deprived these men of “demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available,” causing the unnecessary disability and death of the men, their wives, and their children. The trial was not only unnecessary because researchers already knew the course of the disease and its effects, but it was also dangerous because researchers withheld information and treatment, which allowed syphilis to spread to the men’s wives and children. Thus, there was nothing gained from the trial other than exploiting the economically disadvantaged and minorities.

To put an end to the exploitation of the economically disadvantaged and minorities, the Belmont Report incorporated informed consent into the “respect for persons” principle. Under this principle, researchers must respect the wishes of persons who are autonomous and capable of self-deliberation. To respect their autonomy, researchers must “give weight to the autonomous persons’ considered opinions and choices while refraining from obstructing their wishes unless they are clearly detrimental to others.”<sup>9</sup> This respect of autonomy is fulfilled when researchers inform all research subjects about the risk of participation in the clinical trial and obtain the subjects’ *voluntary* consent to participate. In order to be *voluntary*, the decision to participate in the clinical trial must be free of undue influence. Undue influence “occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance,” and includes “action(s) such as manipulating a persons’ choice by threatening to withdraw health services to which an individual would otherwise be entitled.”<sup>10</sup> According to British philosopher Onora O’Neil, the main purpose of informed consent is to ensure that a research subject has not been unduly influenced into participating in clinical trials.<sup>11</sup>

In 1986, the Belmont Report in its entirety, was adopted by sixteen federal agencies and departments, including HHS, and codified in 45 C.F.R Part 46 (the Common Rule). To fulfill the requirements of the “respect for persons” principle, the Common Rule mandates that researchers draft and have all research subjects sign a consent form, which includes, “A statement that participation is *voluntary*, refusal to participate will involve no penalty or loss of benefits to

which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.”<sup>12</sup> Institutions receiving federal funding to conduct clinical trials must enter into a contractual agreement with the federal government, called an assurance,<sup>13</sup> asserting that they will comply with the Common Rule requirements, such as informed consent. Once an institution’s assurance is approved and it receives federal funding, the federal government requires that all research conducted by the institution regardless of who funds it comply with 45 C.F.R Part 46. Hence, the Common Rule governs nearly all research studies conducted by or funded by the federal government, except for studies conducted in emergency settings.<sup>14</sup>

The Office for Human Research Protections (OHRP), a federal agency within HHS, is responsible for ensuring that institutions comply with their assurances and the Common Rule.<sup>15</sup> To fulfill this task, OHRP conducts site visits. These visits can be random or in response to allegations of noncompliance with the Common Rule.<sup>16</sup> When reviewing allegations of noncompliance, OHRP grants the institution an opportunity to refute the allegations. Once additional information is obtained, OHRP determines whether the institution has violated the law. OHRP issues corrective action for instances of noncompliance, which is in “the best interest of human research subjects, and to the extent possible, the institution, the research community, and HHS.”<sup>17</sup> Corrective action may include restriction or withdrawal of approval for an institution’s assurance and suspension or permanent removal from participation in specific projects.<sup>18</sup> Information regarding allegations and findings of noncompliance can be found on OHRP’s website.

OHRP is responsible for reviewing compliance at the institutional level. Every institution that has an assurance is responsible for ensuring that individual clinical trials conducted by those affiliated with the institution comply with the Common Rule. To accomplish this task, all institutions and federal agencies that enter into an assurance have an Institutional Review Board (IRB). Before researchers can conduct clinical trials using human subjects in the United States or be funded by the United States government to conduct clinical trials using human subjects, they must submit a research protocol to their IRB.<sup>19</sup> A complete research protocol includes a statement of compliance with the ethical principles, such as the “respect for persons” principle.<sup>20</sup> The IRB reviews all written research protocols in application for clinical trials using human subjects to ensure that the proposed studies are ethical. If the IRB finds that the research protocol is ethi-

cal, they can approve the research to be conducted and/or submitted for funding to the United States government. The IRB can also require modifications in the research protocol or disapprove any research protocol.<sup>21</sup>

In terms of the “respect for persons” principle, the IRB is required to ensure that all consent forms for participation in clinical trials include “a statement that participation is *voluntary*, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discon-

Notwithstanding the requirements of the Belmont Report, the Common Rule, and the Guidebook, minorities and the economically disadvantaged continue to be unduly influenced into participating in clinical trials in violation of the “respect for persons” principle. Although, the “respect for persons” principle standard is a significant protection when health care is accessible, it has little direct application when health care access is scarce and medical resources are very limited. For example, the researchers in the Tuskegee Syphilis Study clearly failed to obtain informed con-

**By offering access to health care to research subjects, the researchers were inducing them to participate in the clinical trial because that was the main way African Americans could obtain access to health care. Hence, the African Americans’ consent was not *voluntary*. Minorities and the economically disadvantaged still face significant barriers to accessing health care because of class and racial biases, even after the passage of the Patient Protection and Affordable Care Act (ACA).**

tinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.”<sup>22</sup> Thus, in accordance with the Common Rule, the IRB is required to ensure that no researcher uses research subjects who have not *voluntarily* consented to participation in the clinical trial. If the IRB allows subjects to participate involuntarily, the institution is in violation of their assurance and subject to corrective action by OHRP. Not only does the “respect for persons” principle apply to research conducted in the United States or funded by the United States government, but it also governs research used to seek drug approval by the U.S. Food and Drug Administration (FDA).

In addition to the Common Rule, OHRP issued a non-binding guidance to assist IRBs in fulfilling their responsibilities in protecting the rights and welfare of human subjects. Among other things, the Guidebook focuses on the need for protecting vulnerable populations, such as minorities and the economically disadvantaged, from undue influence that negates voluntary consent. Specifically, the Guidebook notes that researchers need to be aware that consent is not *voluntary* when there is real or perceived belief that participation is necessary to receive continuing care from health professionals or because the receipt of any treatment is perceived as preferable to receiving no treatment.<sup>23</sup> Thus, seemingly, the lack of meaningful choice when it comes to accessing health care makes consent involuntary.

sent by lying to the men about the study. However, even if the researchers had not lied about the study, the informed consent would not have been *voluntary* during the first 32 years of the study. During this time, the U.S. government (state and federal) mandated and funded racially separate and unequal health care facilities, often barring African Americans from accessing health care. By offering access to health care to research subjects, the researchers were inducing them to participate in the clinical trial because that was the main way African Americans could obtain access to health care. Hence, the African Americans’ consent was not *voluntary*. Minorities and the economically disadvantaged still face significant barriers to accessing health care because of class and racial biases, even after the passage of the Patient Protection and Affordable Care Act (ACA).

### **III. Social Context: Class and Racial Biases**

In the United States, class and racial biases, actions based on negative pre-judgment against a person or group based on socioeconomic status or race, persist. These biases predict differential access to resources such as income and wealth. Often relegated to impoverished and racially segregated neighborhoods, minorities and the economically disadvantaged attend low-quality schools, keeping them unemployed, underemployed, or in jobs without health insurance. Without these resources, minorities and the economi-



cally disadvantaged are prevented from accessing health care.<sup>24</sup>

Among other categories, income and wealth inequalities are used to measure class and racial biases. According to the U.S. Census Bureau's 2014 report, the top 5% of households receive about 21.8% of the income, while the bottom 60% received 27.8% of the income.<sup>25</sup> Furthermore, the richest 20% of U.S. families accounted for 88.9% of all wealth in the United States and the highest earning 20% of U.S. families earned 61.8% of all income in the United States.<sup>26</sup> In fact, in 2013, the median wealth of U.S. upper income families was \$639,400 compared to \$96,500 for middle-income families, and \$9,100 for low-income families, the widest gap in 30 years.<sup>27</sup> When you add in the race factor, economically disadvantaged minorities are more likely to live in neighborhoods with a high degree of poverty compared to economically disadvantaged Caucasians.<sup>28</sup> By 2008, over half of Hispanics, African Americans, and American Indians and Alaska Natives were economically disadvantaged or near economically disadvantaged compared with 27% of Caucasians and 31% of Asians.<sup>29</sup>

Minorities have higher poverty rates than Caucasians because racial bias prevents them from obtaining the same employment opportunities as Caucasians, limiting their ability to earn income and build wealth. Research also shows that in several industries minorities are paid less than Caucasians doing equal work. For example, minorities, such as African Americans and Hispanics, are often not hired by most of the well-known high-tech firms; however, when they are hired they receive less pay and are passed over for promotions and pay raises. Hispanics make \$16,353 less, Asians make \$8,146 less, and African Americans make \$3,656 less than Caucasians working in the high-tech industry.<sup>30</sup> This disparity in earnings affects wealth, leading to racial gaps.

Following the same households for over 25 years (1984-2009), researchers found that the total wealth gap between Caucasian and African American families nearly tripled, increasing from \$85,000 in 1984 to \$236,500 in 2009, a difference of \$152,000.<sup>31</sup> The study also showed that in 2009 the median wealth of Caucasian families was \$113,149 compared with \$5,677 for African American families, a difference of almost \$108,000. Researchers found that approximately 66% of the wealth gap between African Americans and Caucasians was a result of racial bias, which causes racial inequalities in homeownership, income, employment, education, and inheritance.

For instance, even when African Americans graduate from college, employment inequalities persist. Indeed, in 2009, the Bureau of Labor Statistics showed

that the unemployment rate for African American male college graduates was 8.4 percent compared to 4.4 percent for Caucasian college graduates.<sup>32</sup> This rate is due in part to racial bias. Studies show that African Americans seeking employment have a harder time obtaining employment because non-African American managers tend to hire more Caucasians. Also, African Americans with non-Caucasian-sounding names received 50 percent less callbacks than African Americans with Caucasian sounding names. Thus, it is not surprising that in 2015 unemployment rates were 9.5% for African Americans compared to 4.6% for Caucasians.<sup>33</sup> Income and wealth inequality directly affect access to health care by minorities and the economically disadvantaged because health care is delivered based on ability to pay.

#### **IV. Barriers to Care in the Health Care System**

Structural bias operates at the societal level, denying some groups access to the resources of society, while privileging other groups.<sup>34</sup> Institutional bias operates through organizational structures and establishes 'separate and independent' barriers through the neutral denial of access to health care that results from the normal operations of the institutions in a society. While seemingly similar, there is a significant difference between structural and institutional bias. Institutional bias focuses on the direct effects of institutional actions on minorities and the economically disadvantaged, whereas structural bias measures how non-class and non-race based factors, such as the delivery of health care, indirectly effects minorities and the economically disadvantaged.

##### *a. Structural Bias*

Structural bias is a result of power relationships between racial and socioeconomic groups, where one dominant group holds power over the other group and uses that power to secure material and social resources, such as income and wealth. The dominant group remains in power because its position in society enables it to retain power despite the will or aims of the groups it has power over. In health care, an example of structural bias is the delivery of health care based on ability to pay.

As a result of this bias, those with privilege, such as wealthy Caucasians, obtain the best quality health care available. The privileged obtain access because they are able to afford health insurance or pay for health care not covered by insurance. Those without privilege, such as minorities and the economically disadvantaged, have limited access to health care because they do not have health insurance or they cannot afford

to pay for health care.<sup>35</sup> For instance, African Americans and Hispanics are more likely than Caucasians to work in low-wage jobs that do not offer employer-sponsored health insurance. Consequently, minorities are more likely than Caucasians to be uninsured or underinsured, which has not changed significantly with the passage of the ACA.

In the first open enrollment period of the ACA (2013-2014), the percentage rates of uninsured fell significantly for economically disadvantaged adults (from 35% to 24%) and Hispanics (from 36% to 23%).<sup>36</sup> Yet, in 2014, 33 million people (10.4%) were still without health insurance. In 2014, employment-based health insurance covered 55.4% of the U.S. population, Medicaid covered 19.5% of the U.S. population, Medicare covered 16% of the U.S. population, direct-purchase health care covered 14.6% of the U.S. population, and military health care covered 4.5% of the U.S. population.<sup>37</sup> Nevertheless, minorities and the economically disadvantaged still remain uninsured at a higher rate than those who are privileged because of the failure of those in power in nineteen states to expand Medicaid coverage.

As of January 2016, Washington, D.C., and 31 states have expanded Medicaid to cover economically disadvantaged adults. However, in the 19 states that did not expand Medicaid, the economically disadvantaged remain without health insurance because their employer does not provide coverage, they earn too much to qualify for Medicaid, and they do not earn enough to qualify for tax credits to purchase health insurance on their own.<sup>38</sup> Approximately three million economically disadvantaged adults remain uninsured because of the failure to expand Medicaid, and they reside in states with the largest uninsured population such as Texas, Florida, Georgia, and North Carolina. These adults work in part-time jobs, jobs for employers with less than 50 employees (so not covered by the ACA penalties), or jobs that do not provide health insurance like those in the agriculture and service industries. Because minorities are more likely than Caucasians to work in these jobs and live in families with low incomes, they disproportionately remain uninsured due to the failure to expand Medicaid. In fact, minorities make up over half of the uninsured, while only accounting for forty percent of the U.S. population.<sup>39</sup>

Even if minorities and the economically disadvantaged obtain health insurance, they still lack access to health care because they are underinsured, meaning they have to pay high deductibles or out of pocket for medical costs, which they cannot afford. According to a Commonwealth Fund report, in 2014 over 31 million people were underinsured, about 23% of those had year-round health insurance.<sup>40</sup> Of the underin-

sured, 44% reported forgoing care because of the cost, and 51% reported having problems paying medical bills or debts, totaling \$4,000 or more. People with low incomes under 200 percent of the federal poverty line, accounted for 61% of underinsured adults in the United States. By 2015, the U.S. Census Bureau reported that 46.7 million people (14.8%) were in poverty in the United States. The poverty rate has increased from 2007-2011, when the U.S. Census Bureau reported that 42.7 million people (14.3%) had incomes below the poverty line.<sup>41</sup> The rate of poverty for African Americans was 25.8%, 23.2% for Hispanics, and 11.6% for Caucasians.<sup>42</sup>

Living in poverty, minorities and the economically disadvantaged, who do not generally have health insurance or are underinsured, are charged more for the health care services they receive and are increasingly required to pay upfront for the care they receive. However, the wealthy, who usually have health insurance, receive discounts on the cost of health care, negotiated by their insurers. Under the ACA, non-profit hospitals can no longer charge uninsured patients more than they generally bill insured patients for emergency and other medically necessary care.<sup>43</sup> Unfortunately, this still leaves the uninsured (predominately minorities and the economically disadvantaged) unprotected because the policy does not apply to for-profit hospitals, which account for up to 40% of all hospitals in the United States.

Additionally, the ACA does not equalize the care provided minorities or the economically disadvantaged when compared to the wealthy. A 2012 *New York Times* article noted that affluent patients, who pay in cash, can stay in elite hospital wings that offer marble baths, butler service, and bed linens by "Frette, Italian purveyors of high-thread-count sheets [sold] to popes and princes."<sup>44</sup> Yet, the article noted that one patient who could not afford the elite rooms was left in pain, on a gurney, without a bedpan. Nothing in the ACA mandates equal quality care be provided to those receiving health care services from the same health care provider. Institutional bias also prevents access to health care for the economically disadvantaged and minorities, because health care institutions are allowed to decide what hospitals to close and who qualifies for charity care.

#### *b. Institutional Bias*

Examples of institutional bias within the health care system include hospital closures in minority neighborhoods and lawsuits against the economically disadvantaged for unpaid care; both further limit access to health care. Not all actions by an institution that disproportionately affect minorities and the economi-

cally disadvantaged are biased. In order to constitute institutional bias, the action must reinforce the racial and/or class hierarchy and impose substantial harm on minorities and the economically disadvantaged. Once this occurs, then the institution's actions constitute institutional bias even if the actions are seemingly neutral.

Shortly after the passage of the Civil Rights Act of 1964, hospitals in African American communities closed and relocated to affluent Caucasian neighborhoods.<sup>45</sup> In 1992, a report of 190 urban community hospitals between 1980 and 1987 found that the percentage of African American residents in the neighborhood was the most significant factor in hospital closures.<sup>46</sup> In 2006, Alan Sager reported that as the African American population in a neighborhood increased, the closure and relocation of hospital services increased for every period between 1980 to 2003, except between 1990 and 1997.<sup>47</sup> Hence, research shows that as the percentage of African American residents increased in the neighborhood, hospital closures increased.

In fact, Dr. Sager has shown that 45% of hospitals open in 1970 had closed by 2010, and of these hospitals 60% were in neighborhoods that were predominately African American.<sup>48</sup> St. Louis and Detroit are poignant examples of hospital closures linked to race. St. Louis had 18 hospitals in predominately African American neighborhoods. By 2010, all but one had closed. In 1960, Detroit had 42 hospitals open in predominately African American neighborhoods; by 2010 only four were open. This reduction of hospital beds in African American communities, which generally have the greatest need for care, further compromises African Americans' health by decreasing their access to health care.<sup>49</sup>

As hospitals leave predominately African American neighborhoods, the remaining hospitals are left to fill the void. This often strains the remaining hospitals' resources and their ability to provide quality care. Consequently, the hospitals that do remain to provide care to African Americans gradually deteriorate and provide substandard care. Not only is access to health care diminished because of a reduction of hospital services, but care also suffers because of physician departures. Once a hospital has closed or relocated, the physicians practicing in the area often follow the hospital to more affluent neighborhoods, thereby further disrupting access to health care services in predominately African American neighborhoods. Evidence shows that primary care physicians often leave after the closure of a neighborhood hospital because the hospital provides a critical base for their practice. This disruption in care is significant because many

predominately African American neighborhoods already suffer from physician shortages prior to hospital closures and physician flight.<sup>50</sup> As the number of primary care physicians decreases, African Americans are forced to seek care in emergency rooms and public hospitals, which are often understaffed and not adequately maintained. Thus, the institutional decision to close hospitals in predominately African American neighborhoods substantially harms African Americans and reinforces the racial hierarchy that African American lives do not matter.

In addition to the lack of health care services available in minority neighborhoods, some non-profit hospitals erect barriers to care for the economically disadvantaged by suing them for unpaid medical bills. These practices have continued even after the passage of the ACA, which tried to limit these aggressive collection practices. Numerous nonprofit hospitals in Ohio, Minnesota, Missouri, New York, North Carolina, and Texas, have sued patients for unpaid bills even though many of the patients are economically disadvantaged and could qualify for charity care, which would discharge their bills.

For example, in North Carolina, non-profit hospitals have filed more than 40,000 collection lawsuits in a five-year period. Carolina HealthCare system, a health care system that manages two non-profit hospitals Moses Cone Health System and Wilkes Regional Center, has filed over 12,000 lawsuits in a five-year period, while having over \$150 million in annual profits and enjoying \$100 million in tax breaks.<sup>51</sup> Many of the patients who were sued for unpaid bills were uninsured and economically disadvantaged. Once the hospital wins the case and receives a judgment against the patient, it usually places a lien on the patient's house. Due to the lawsuits, the economically disadvantaged patients cannot sell their homes, are pushed further below the poverty line, have their credit report scores decline, and forgo medical care because they are worried about future liens being placed on their homes. This substantially harms them and reinforces the class hierarchy that the lives of the economically disadvantaged do not matter.

Due to class and racial biases in the U.S. and structural and institutional bias within the health care system, minorities and the economically disadvantaged are denied access to health care because they are uninsured, underinsured, or unable to pay for health care. As a result of forgoing health care, minorities and the economically disadvantaged are often more likely to be disabled or in poor health and vulnerable to inducements to participate in clinical trials to obtain access to health care.



### V. The Effect of Bias: Burdened with Disease

Due to the lack of access to health care, minorities and the economically disadvantaged have higher rates of disease and disability. Burdened with greater rates of disease and disability, minorities and the economically disadvantaged are a panacea for researchers investi-

in the form of redlining policies that prevent racial integration has resulted in racial segregation of neighborhoods.<sup>56</sup> The racially segregated neighborhoods that are predominately African American usually have less economic investment, but they have more stressors such as pollution, noise, overcrowded housing

Due to the lack of access to health care, minorities and the economically disadvantaged have higher rates of disease and disability. Burdened with greater rates of disease and disability, minorities and the economically disadvantaged are a panacea for researchers investigating medical advancements and trying to obtain generalizable scientific knowledge. Without meaningful access to health care, minorities and the economically disadvantaged are induced into participating in clinical trials that may provide a benefit to society, but will not alleviate their increased rates of disease or disability due to bias.

gating medical advancements and trying to obtain generalizable scientific knowledge. Without meaningful access to health care, minorities and the economically disadvantaged are induced into participating in clinical trials that may provide a benefit to society, but will not alleviate their increased rates of disease or disability due to bias.

For instance, racial bias results in increased stress for African Americans that impairs their health status. Studies have shown that both U.S. born and foreign born African American women, who have experienced racial bias, were more likely to have hypertension or hypertension events.<sup>52</sup> In fact, African American women who had experienced racial bias and had chosen not to object to it were 4.4 times more likely to have hypertension than those who stated that they took action or talked to somebody. Moreover, research suggests that there is a higher positive correlation between perceived racial prejudice and increased cigarette and alcohol use among African Americans as compared to Caucasians.<sup>53</sup> The increased stress from perceived racial bias also affects birth outcomes by increasing African Americans' rates of infant mortality.<sup>54</sup> Finally, research has shown that experiencing racial bias accelerates the biological aging of African American men, which may lead to their lower life expectancy.<sup>55</sup>

In addition to the direct biological effects of racial bias that cause increased rates of disease and disability, racial bias also indirectly increases African Americans' rates of disease and disability. For example, racial bias

stock, and high rates of crime.<sup>57</sup> These neighborhoods also have fewer resources such as places to exercise or play, which increases African Americans' rates of disease and disability. For instance, researchers have found that the presence of one or more health clubs as well as lower crime rates were both directly associated with lower cardiovascular disease risk for the African American women in their study.<sup>58</sup>

Furthermore, in racially segregated neighborhoods, "residents do not have access to healthy food due to a lack of supermarkets and a preponderance of convenience stores and fast food restaurants as the primary food outlets," all of which have been shown to lead to obesity, a risk factor for cancer and cardiovascular disease.<sup>59</sup> Racial segregation also affects the place that African Americans receive care. In racially segregated neighborhoods, African Americans are more likely to undergo surgery in low-quality hospitals, whereas in areas with low degrees of racial segregation, African Americans and Caucasians are likely to undergo surgery at low quality hospitals at the same rate. This is significant because among Medicare patients, most of the racial disparities in risk-adjusted death rates for major surgery are a result of the site of care.<sup>60</sup>

The economically disadvantaged also experience disparities in health status because of bias related to poverty and their lack of health insurance. In fact, "[e]ven percent of the uninsured are in fair or poor health, compared to [five percent] of those [covered by private health insurance]."<sup>61</sup> Studies also show that uninsured women with breast cancer are diagnosed

later during its development, when treatment is less effective.<sup>62</sup> Increasing the likelihood of serious harm, uninsured men with hypertension are more likely to go without screenings and prescribed medication and to skip recommended doctor visits. Data from the Institute of Medicine's (IOM Report) 2002 report, *Caring Without Coverage: Too Little, Too Late*, showed that, on average the uninsured only received about half the care that privately insured patients received, and the uninsured tended to wait longer and get sicker before seeing a doctor.<sup>63</sup>

Moreover, the uninsured are less likely to receive recommended preventive and primary care services, face significant barriers to care, and ultimately face worse health outcomes.<sup>64</sup> Compared to the insured, a larger share of the uninsured are unable to pay medical bills. In addition, the uninsured report problems procuring dental care, filling a prescription due to cost, and accessing physician care.<sup>65</sup> Being economically disadvantaged and uninsured is worse for minorities. For example, between 2005 and 2006, "[t]he largest difference in doctor visits between insured and uninsured populations was seen among African-Americans and individuals of two or more races."<sup>66</sup> This racial difference in physician visits is not new; in 1986, for example, a national survey of the use of health care services found that "[e]ven after taking into account persons' income, health status, age, sex, and whether they had one or more chronic or serious illnesses, blacks have a statistically significantly lower mean number of annual ambulatory [walk-in] visits and are less likely to have seen a physician in a year."<sup>67</sup> Left without access to health care and overburdened with disease and disability, minorities and the economically disadvantaged are vulnerable to undue influence to participate in clinical trials offering access to health care.

## VI. Undue Influence in Clinical Trials

Professor Patricia King, one of the drafters of the Belmont Report, noted, "[d]espite common recognition that 'the Tuskegee Study is America's metaphor for (racial) discrimination in medical research,' there has been inadequate attention paid to race, either in the sense of negative and differential treatment or in terms of pervasive scientific (racial) discrimination, in the construction of bioethics in the United States."<sup>68</sup> Specifically, neither researchers nor those who regulate clinical trials take into account racial and class biases that make the consent of minorities and the economically disadvantaged involuntary because of undue influence. Illustrative of this problem is the behavior of researchers in selecting research subjects.

Researchers from health care institutions that deny minorities and the economically disadvantaged access to health care, use these same populations as subjects for clinical trials. The promise of access to health previously denied, unduly influences minorities and the economically disadvantaged to participate in clinical trials. Below are two examples of instances in which minorities and the economically disadvantaged were unduly influenced to participate in clinical trials in violation of the "respect for persons" principle.

### *a. Lawsuits, Patient Dumping, and Clinical Trials*

Researchers who conduct clinical trials using minorities and the economically disadvantaged are often affiliated with health care institutions that prevent access to health care for minorities and the economically disadvantaged. Access to care is limited by lawsuits and denials of nonemergency and/or emergency care. If participation in clinical trials is the only way minorities and the economically disadvantaged can gain access to health care, they are not making *voluntary* decisions to participate in clinical trials because they have no other choice in order to gain access to health care.

For example, Heartland Regional Medical Center, a nonprofit hospital in Missouri that receives tax breaks in exchange for providing care to the economically disadvantaged, has sued approximately 6,000 patients for unpaid bills from 2009-2013, even though some of the patients should have qualified to have their bills forgiven.<sup>69</sup> Once the hospital wins the case and receives a judgment against the patient, it usually adds 9% interest to the bill and garnishes the wages of the patient and the patient's spouse collecting up to 35% of their wages. The hospital has also taken liens out on a patient's home to recoup the costs of any judgment exceeding \$1,000. In 2013, the hospital made \$605 million in gross revenues, \$45 million of which was profit, yet it filed over 2,200 lawsuits for medical debts. Garnishments amount to 0.5% of the hospitals revenues. As a result of these institutionally biased practices, many economically disadvantaged patients cannot sell their homes, are pushed further below the poverty line, have their credit report scores decline, and forgo medical care because they are worried about future wage garnishments and liens being placed on their homes. Notwithstanding the lawsuits filed to collect unpaid hospital bills from the uninsured and economically disadvantaged, Heartland Regional Medical Center recruits some of these patients to participate in the clinical trials, which offer access to free health care as an incentive.

In addition to the financial barriers to care, many hospitals limit the treatment of economically disad-

vantaged patients, often redirecting them to community hospitals or clinics, while using them as research subjects in clinical trials. The University of Chicago Medical Center (Center) is a perfect example of this tension between limiting care to minorities and the economically disadvantaged, while focusing on expanding clinical trials using these populations. In 2009, the Center adopted policies to redirect people, suffering from non-urgent injuries and illnesses, who lived in the neighborhoods surrounding the hospital to community hospitals and clinics.<sup>70</sup> Because the hospital is located in an impoverished area that is racially segregated, the people being redirected were disproportionately economically disadvantaged minorities. However, when the Center needed subjects for clinical trials, these people were solicited for participation in the trials because of their proximity to the hospital.<sup>71</sup>

Denials of access to health care occur even when care is required. Under the Emergency Medical Treatment and Active Labor Act (EMTALA), hospitals are required to provide a screening examination to determine if a person is experiencing an emergency condition or in active labor.<sup>72</sup> If the patient is experiencing an emergency condition or in active labor, the hospital, regardless of the patient's ability to pay, is required to stabilize the patient, admit the patient, or complete an appropriate transfer to another facility. Unfortunately, some hospitals violate EMTALA by denying care to patients based on ability to pay, but then seek to use these same patients in clinical trials. For instance, in 2009, the Center tried to limit the number of inpatient beds available to emergency room patients and failed to provide care to those with urgent care injuries. Although the policies were not fully implemented after two physician groups voiced their concerns, the hospital still failed to provide care to patients with urgent care injuries and was fined \$50,000 as a result of the death of a patient waiting in the emergency room.<sup>73</sup> As discussed above, the Center still uses these people in clinical trials.

In the United States there is no mandate to treat. Hence, the lawsuits for unpaid care, redirecting of patients, and outright denials of care by health care institutions prevent minorities and the economically disadvantaged from accessing health care. Thus, when researchers from these same institutions offer access to health care to minorities and the economically disadvantaged if they participate in clinical trials, the researchers are unduly influencing these populations to participate in clinical trials because they have no other choice in order to access health care. This inducement to participate in clinical trials is a violation of the "respect for persons" principle.

#### *b. HIV/AIDS Drug Clinical Trials*

For 13 years (1988-2001), Illinois, Louisiana, Maryland, New York, North Carolina, Colorado, and Texas enrolled foster children aged 3 months to late teens in Phase I and II drug trials for the treatment of the Human Immunodeficiency Virus and the Acquired Immune Deficiency Syndrome (HIV/AIDS).<sup>74</sup> Funded in part by the National Institutes of Health, the trials were conducted to determine the drug toxicity and adverse side effects of potential HIV/AIDS drugs. There were a plethora of problems with the studies, including the failure to obtain consent for every child that participated, a violation of the "respect for persons" principle.<sup>75</sup> Even though children cannot give informed consent, the "respect for persons" principle requires that a parent or guardian consent to the child's participation in clinical trials, except in emergency settings.<sup>76</sup>

The majority of the children used for the study were African American or Hispanic, economically disadvantaged, and foster children that were wards of the state or without a guardian. The enrollment of children in the HIV/AIDS drug trials was particularly objectionable because not only did the researchers fail to obtain voluntary consent, but also the children used in the HIV/AIDS drug studies were not even tested for HIV/AIDS. Thus, the states and researchers exposed *healthy* children "to risks of medical research and drugs that were known to have serious side effects in adults and for which the safety for children was unknown."<sup>77</sup>

For example, during an Illinois study of dapsone, a drug to prevent AIDS-related pneumonia, "researchers reported some children had to be taken off the drug because of 'serious toxicity,' others developed rashes, and the rates of death and blood toxicity were significantly higher in children who took the medicine daily, rather than weekly." The researchers noted that for the period of the study "at least 10 children died from a variety of causes, including four from blood poisoning, and researchers said they were unable to determine a safe, useful dose. They said the deaths didn't appear to be 'directly attributable' to dapsone but nonetheless were 'disturbing.'" Nevertheless, this study and others continued even after 1990 when Azidothymidine, better known as AZT, was shown to be an effective treatment for HIV/AIDS without severe side effects. In addition to this use of minority and economically disadvantaged children in hazardous drug trials, some researchers failed to obtain proper consent from participants in the trials.

There were two common practices that violated the informed consent laws. First, many of the researchers failed to obtain consent from an authorized person,

such as an independent advocate, for each child. For example, none of the 200 Illinois foster children participating in the trials were appointed independent advocates even though researchers signed a document guaranteeing “the appointment of an advocate for each individual ward participating in the respective medical research.” In New York, advocates were only appointed to one-third of the 465 foster children participating in the trials, and in some instances children between five and ten years of age were asked to sign consent forms once they were told of the risks and benefits of the trials. Second, if consent was obtained from an authorized person it was based on incorrect information. Researchers obtained blanket consent for participating foster children from state welfare agencies based on the premise that the research had minimal risks and the children would directly benefit from the research. In fact, government officials in Illinois and New York gave blanket consent and exempted themselves from the requirement of appointing independent advocates to provide consent because the researchers claimed the trials would have only minimal risks and the children would directly benefit. However, this information was clearly incorrect because the drugs being tested were known to cause serious side effects in adults, so the risk was more than minimal to the children, and there was no direct benefit to the children participating in the trials because they were healthy and more than likely not infected with HIV/AIDS.

Even though presented with overwhelming evidence of the lack of consent in all these trials, OHRP only noted a problem with the clinical trials in New York. Moreover, OHRP did not investigate whether the consent was voluntary. Although the children were wards of the state with access to health care, they did not have access to HIV/AIDS drugs. Thus, it seems as if the state was unduly influenced into giving consent for the children’s participation in clinical trials based on the promises of access to these drugs. However, the states gave blanket consent for the use of these children instead of reviewing the files of each child to see if the child was actually infected with HIV/AIDS. Hence, OHRP should have noted that the consent was involuntary and put an end to the research studies immediately.

However, as Carol Levine notes, “there has been no resolution of the conflict between American society’s failure to provide basic health care and HIV/AIDS prevention programs to poor communities of color—a matter of social justice—and the potential coerciveness of using research participation as an entry into the health care system.”<sup>79</sup> The use of these children was a violation of the “respect for persons” principle

because, among other things, the researchers unduly influenced the states into providing consent for these children by promising access to health care. To ensure that subjects are not being unduly influenced into participating in clinical trials, I suggest that researchers be required to complete a Vulnerability and Equity Impact Assessment (VEIA) tool, based in part on the Health Equity Impact Assessment (HEIA) tool.

## VII. Solution

The VEIA should be used to assess whether the proposed research subjects are being unduly induced to participate because they lack access to health care, which is a violation of the “respect for persons” principle. The VEIA requires researchers to identify the biases in society, including class and race, and the biases in the health care system, such as structural and institutional biases, that prevent minorities and the economically disadvantaged from obtaining access to health care, and then determine whether the biases bar minorities and the economically disadvantaged from participating in clinical trials. The completed tool should be posted on [clinicaltrials.gov](http://clinicaltrials.gov) and used by the IRB to determine if the study has fulfilled the requirements of the “respect for persons” principle from the Common Rule.

### a. Combatting Bias

Since the 1970s, the Health Impact Assessment (HIA) has been used as a tool to assess the potential effects of a policy on the health of a population. Although the HIA can determine if the policy will have impacts on different social groups, the process does not provide information concerning whether these differential impacts are a result of unfair and biased policies. Consequently, the HEIA was created to ensure that assessments about a policy’s impact would include an evaluation of fairness and equity as well as root causes of inequities.

The HEIA identifies the root causes of health inequity, such as wealth, income, knowledge, and power imbalances. There are five purposes of a HEIA:

1. “Help identify potential health impacts (positive or negative) of a plan, policy or program on vulnerable or disadvantaged groups within the general population.
2. Help develop recommendations as to what adjustments to the initiative might mitigate negative impacts as well as maximize positive impacts on the health of vulnerable and disadvantaged groups.
3. Embed equity across an organization’s existing and prospective decision-making models,



so that it becomes a core value and one criterion to be weighed in all decisions.

4. Support equity-based improvement in program/service design: ‘How does this program need to be adjusted to meet the needs of specific populations?’ ‘Could this program benefit some, but not others?’
5. Raise awareness about health equity as a catalyst for change throughout the organization, so planners and managers develop ‘stretch goals’: How can we include more people in this program, especially those often missed? What barriers do we have to look for? Are we as effective as we could be, especially those with the greatest and most complex health needs?”<sup>80</sup>

When completing a HEIA, the following five steps must be completed:

### 1. “Screening:

- a. Determine if the initiative requires a HEIA. If the initiative has the potential to impact the health of vulnerable or disadvantaged groups, HEIA is applicable. It is desirable that all initiatives be screened.

### 2. Scoping:

- a. Identify affected populations or groups and predict key impacts (positive or negative) on those groups. Consider a wide range of vulnerable or disadvantaged groups to avoid overlooking unexpected or unintended consequences of an initiative.

### 3. Impact Assessment:

- a. Use available data/evidence to prospectively assess the impact on vulnerable or disadvantaged groups in relation to the broader target population. It is both useful and important to consider a broader range of evidence including consultation findings and grey literature (including project or program reports, informal practice guidelines, recommended or promising practices). These sources of evidence should be weighed based on their strength and quality.
- b. Where there is very limited data/evidence available, note the lack of evidence in the assessment or, where possible, implement other strategies to gather evidence. Strategies could include conducting surveys, focus groups, or consultation with experts or

members of the affected groups where time permits.

### 4. Mitigation Strategy:

- a. Develop evidence-based recommendations to minimize or eliminate negative impacts and maximize positive impacts on vulnerable or disadvantaged groups. These recommendations comprise your mitigation strategy. Uptake of these recommendations in the roll out of the initiative will help to ensure that the initiative contributes to equity and does not perpetuate or widen existing health disparities. Where possible, recommendations should be informed by diverse members of the affected communities.

### 5. Monitoring and Evaluation:

- a. Determine how the rollout of the initiative will be monitored to determine its impacts on vulnerable or disadvantaged groups in comparison to other subpopulations or the broader target population. The resulting data will enhance the overall evidence base for equity-based interventions and can be fed back into the planning, policy or program development process.”<sup>81</sup>

Once these steps have been completed, the organization must decide whether to implement the policy. Similar to the steps necessary to complete a HEIA, the VEIA would require researchers to complete five steps in order to show whether consent to participation in clinical trials is voluntary.

#### *b. VEIA: Measuring Voluntariness*

To complete the VEIA, researchers would need to *screen* the research proposal to identify the purpose of the research, those affected by the condition being studied, the potential research subjects, and whether the research is a priority to the potential research subjects. If the potential research subjects are minorities and/or the economically disadvantaged, researchers also need to identify the barriers to accessing health care for these populations and whether obtaining access to health care is the central reason the populations would participate in clinical trials. If it is, the researcher must discuss in their research proposal, why they feel the need to use these populations and how they will work to eliminate the barriers to accessing health care for these populations. This review can be incorporated into the current requirement of showing that the research will add to the generalizable scientific knowledge.



In order to answer these questions, the researcher must engage someone from the vulnerable population the researcher plans to use as research subjects. Once this introspective review, or *screening*, has occurred and is noted in the research proposal, then the researcher must complete the *scoping*, *impact assessment*, and *mitigation strategy* steps.

To complete the *scoping* step, the researcher must answer the following questions:

1. What populations are most affected by the condition being studied?
2. Even if minority and economically disadvantaged populations are most affected by the condition, are there other less vulnerable populations that can be used for the research?

If minorities and/or the economically disadvantaged are populations most affected by the condition, then the researcher must assess whether the impacts on these populations are negative or positive. To complete the *impact assessment*, researchers must use all available data, such as empirical research studies. If there is limited data available, then the researcher should collect data by “conducting surveys, focus groups, or consultation with experts or members of the affected groups where time permits.”<sup>82</sup> The evidence should be used to answer the following questions:

1. Disparities:
  - a. Are there race and/or class disparities in the number of people who suffer the condition?
  - b. Are there race and/or class disparities in the number of people who survive from the condition?
  - c. What quantitative and qualitative evidence of disparities exists?
  - d. Which racial/ethnic groups are currently most advantaged and most disadvantaged by the issues this research seeks to address?
  - e. Which socioeconomic groups are currently most advantaged and most disadvantaged by the issues this research seeks to address?
  - f. Will the research exacerbate these disparities?<sup>83</sup>
2. Barriers to access health care:
  - a. Are there barriers to accessing health care for minorities or the economically disadvantaged who are potential research subjects?
  - b. If so, what are the barriers?
  - c. What are the root causes of these barriers to care?

- d. Will the research address these barriers?
- e. Will the research exacerbate these barriers?

### 3. Adverse Impact:

- a. What adverse impact or unintended consequences could result from this research?
- b. Will the impact or unintended consequences further limit access to health care?
- c. How could the adverse impact be prevented or minimized?
- d. Can the research provide a solution to address barriers to accessing health care?

Using the answers from these questions, the researcher must provide an evidence-based determination of whether members of a minority group or the economically disadvantaged group should be used as research subjects because they will not be unduly influenced. If the researcher decides to use minorities and/or the economically disadvantaged as research subjects even though there is a possibility for undue influence, the researcher must develop a *mitigation strategy* that will minimize or eliminate continued barriers to accessing health care for these populations. If there is a mitigation strategy, the researcher must monitor the actual strategy to determine whether minorities and/or the economically disadvantaged actually gain access to health care outside of participating in clinical trials.

Using the Common Rule, the IRB must review the VEIA for all proposed clinical trials using minorities and/or the economically disadvantaged in the United States to ensure the studies comply with the “respect for persons” principle. Specifically, the IRB would be responsible for reviewing the VEIA for each research proposal to make sure that the study was obtaining voluntary consent from minorities and/or the economically disadvantaged participating in clinical trials. This review must occur before the researcher submits the proposal for funding and drug approval.

Additionally, new penalties need to be imposed if a researcher and/or the institution violates the “respect for persons” principle. Currently, OHRP just issues letters and suspends researchers from federally funded research. Violations of these requirements should also result in fines, loss of federal funding, and denial of drug approval. Researchers that violate the requirements should also face criminal fines.<sup>84</sup> Furthermore, victims of research conducted in violation of the “respect for persons” principle should be granted a private right of action against the institution and the researcher.

If researchers had been required to apply the VEIA, many clinical trials found to violate the “respect for person” principle would never have been funded. For example, if the researchers who conducted the HIV/AIDS

drug studies discussed in section VI had been required to complete the VEIA, it would have shown that the consent was not voluntary. First, the researchers would have been required to *screen* the research to identify the purpose of the research, those affected by the condition being studied, the potential research subjects, and whether the research was a priority to the potential research subjects. Because the potential research subjects were minorities and the economically disadvantaged, researchers needed to identify the barriers to accessing health care for these

care to the children beyond the study would not have minimized this potential harm, and thus, there was no *mitigation strategy* that would make consent voluntary.

### VIII. Conclusion

Due to class and racial biases in the U.S. and structural and institutional biases within the U.S. health care system, minorities and the economically disadvantaged are denied access to health care because they are uninsured, underinsured, or unable to pay for

The time has come to put an end to participation in clinical trials without consent, in areas not exempted by the federal government, by requiring researchers to eradicate barriers to accessing health care if they use minorities and the economically disadvantaged for clinical trials. This will only happen if there is a way to identify and measure undue influence. Thus, the adoption of the VEIA tool to measure undue influence will ensure that minorities and the economically disadvantaged are not prevented from reaching their full health potential because of barriers to accessing health care that are only removed when they are needed for clinical trials. Without the tool, minorities and the economically disadvantaged will continue to be sacrificed for the needs of the powerful and the wealthy.

populations and whether obtaining access to health care was the central reason the populations would participate in clinical trials. The *screening* stage would have shown that the potential to receive access to health care and HIV/AIDS drugs unduly influenced state child welfare agencies to grant consent for these children to participate in clinical trials.

At the time of the studies, participation in clinical trials was the only way to obtain HIV/AIDS drugs, so the research would have been a priority to the children if they were suffering from HIV/AIDS. However, because the children were *healthy*, there was no priority to participate in the clinical trial to obtain access to the medicine. Furthermore, there was no evidence that this research was a priority to *healthy* children in foster care. If the researchers were able to show that it was a health priority, the research would still be prohibited under the *scoping* step because there was no evidence during the time the clinical trials were being conducted that minority and economically disadvantaged children were the group most affected by HIV/AIDS. Therefore, other populations should have been used. Moreover, the *impact assessment* would have shown that the research was too dangerous to conduct on this population because the drugs had severe side effects even for otherwise *healthy* children. Extending access to health

health care. These barriers to access are compounded by health care institutions that deny care to minorities and the economically disadvantaged, and then use this lack of access to health care as a means to influence these populations to participate in clinical trials. Until these biases are addressed minorities and the economically disadvantaged will not have access to health care and will continue to be unduly influenced into participating in clinical trials in violation of the “respect for persons” principle.

Therefore, the time has come to put an end to participation in clinical trials without consent, in areas not exempted by the federal government, by requiring researchers to eradicate barriers to accessing health care if they use minorities and the economically disadvantaged for clinical trials. This will only happen if there is a way to identify and measure undue influence. Thus, the adoption of the VEIA tool to measure undue influence will ensure that minorities and the economically disadvantaged are not prevented from reaching their full health potential because of barriers to accessing health care that are only removed when they are needed for clinical trials. Without the tool, minorities and the economically disadvantaged will continue to be sacrificed for the needs of the powerful and the wealthy.

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