Exploitation in Medical Research: The Enduring Legacy of the Tuskegee Syphilis Study

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EXPLOITATION IN MEDICAL RESEARCH:
THE ENDURING LEGACY OF THE TUSKEGEE SYphilis STUDY

Ruqaiijah Yearby†

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Introduction

For forty years, the United States government allowed economically disadvantaged African American men to be exploited in the name of research, although the research could not generate any benefit to society. Specifically, from 1932 until 1972, government funded researchers enrolled economically disadvantaged African American men in the Tuskegee Syphilis Study to document the already known course of syphilis, which led to the men suffering sores, fever, hair loss, weight loss, headaches, paralysis, blindness, dementia, and death. In exchange for free meals, medical exams, and burial insurance, the researchers promised the men that they would provide treatment for their “bad blood,” which could include “anemic blood to muscle aches, general malaise, disorders such as parasitic infections, gonorrhea, syphilis, and other venereal diseases.” Not only did the researchers lie about the purpose of the study, but also they intentionally deprived these men of “demonstrably effective treatment in order not to interrupt the project, long

1. Throughout the Article, I use economically disadvantaged to discuss children who lack access to essential goods such as food, housing, and health care. Although the term can be over inclusive, for clarity, I have used the word accepted in the medical research community. For more discussion, see Carol Levine, Changing Views of Justice after Belmont: AIDS and the Inclusion of “Vulnerable” Subjects, in The Ethics of Research Involving Human Subjects: Facing the 21st Century 105, 110 (Harold Y. Vanderpool ed., 1996) (“Underlying the protectionist view of the selection of subjects is the assumption that research is risky . . . . If this is true, then subjects should be selected in a way that protects those whose social, demographic, or economic characteristics make them particularly vulnerable to coercion and exploitation.”).


4. Washington, supra note 2, at 162.
after such treatment became generally available," causing the unnecessary disability and death of the men, their wives, and their children.\(^5\) The study was not a therapeutic study because it was not testing a possible treatment of syphilis and blocked any access to treatment.\(^6\) Additionally, the study was not a non-therapeutic study to attain generalizable knowledge because the medical community had already documented the disease process of syphilis.\(^7\) Thus, there was nothing gained from the study other than exploiting economically disadvantaged minorities.\(^8\)

The egregiousness of this study led to the creation and recognition of three Bioethical Principles: Respect for Persons (informed consent);\(^9\)

5. Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 Fed. Reg. 23,192, 23,194 (Apr. 18, 1979) [hereinafter Belmont Report]; Washington, supra note 2, at 159–60, 163. See also Alford Washington, supra note 2, at 177 (“By applying a reproductive justice lens to a reexamination of the Tuskegee Syphilis Study, one ascertains that the government denied the women directly impacted by the study the right to not bear a child with congenital syphilis, because of the government doctors’ intention to study the effect of untreated syphilis on men (the husbands and intimate partners of the women who contracted syphilis) and, unbeknownst to them, passed the disease on to their unborn children.”).

6. See infra note 19 (distinguishing therapeutic from non-therapeutic research studies).

7. See supra note 2.

8. Fred Gray, whose life and work we celebrate with this symposium, filed a lawsuit on behalf of the men who participated in the Study. Fred D. Gray, The Tuskegee Syphilis Study: The Real Story and Beyond 84 (1998). After the lawsuit was filed on July 24, 1973, the government settled the case for approximately ten million dollars ($37,500 to research participants with syphilis who were alive as of July 23, 1973, $15,000 to the heirs of research participants with syphilis, $16,000 to research participants without syphilis who were alive as of July 24, 1973; and $5,000 to the heirs of research participants without syphilis). Id. at 98; Jones, supra note 2, at 216–17. Researchers directly involved in the study never apologized. Id. at 219.

Beneficence (the best interest of the individual participating in the research based on a benefit-risk analysis);¹⁰ and Justice (who participates in medical research and what benefit has to be given to groups who participate in medical research),¹¹ which govern all medical research studies conducted by or funded by the federal government, except for specified circumstances, like emergency settings.¹² Although these Bioethical Principles have the force of law,¹³ medical research studies conducted by or funded by the federal government continue to exploit

“the policy and guidelines on the inclusion of children in research involving human subjects that is supported or conducted by the National Institutes of Health (NIH)); NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIO-MEDICAL & BEHAVIORAL RESEARCH, U.S. DEP’T OF HEALTH, EDUC. & WELFARE, PUBL’N NO. (OS) 77-0004, REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN 43–47 (1977) [hereinafter COMMISSION REPORT] (discussing informed consent in the context of “research involving children”). Paul Ramsey and Richard McCormick provided the most influential discussion regarding autonomy and the use of children in medical research studies. Paul Ramsey argued that there was a need for assent from children participating in medical research studies, and that “no parent is morally competent to consent that his child shall be submitted to hazardous or other experiments having no diagnostic or therapeutic significance for the child himself.” PAUL RAMSEY, THE PATIENT AS PERSON: EXPLORATIONS IN MEDICAL ETHICS 13 (1970). Conversely, Richard McCormick argued that children should participate in medical research studies with parental consent if it would benefit the child, even if only morally, and is a reasonable presumption of the child’s wishes. Richard A. McCormick, Experimentation in Children: Sharing in Sociality, 6 HASTINGS CTR. REP. 41, 41–42, 44 (1976).

¹⁰. See 45 C.F.R. §§ 46.404–407 (2016) (requiring an analysis of the risks and benefits to children as research subjects as a condition to receiving HHS funding or participation); NIH GUIDE, supra note 9 (summarizing “additional requirements under the HHS Regulations 45 CFR 46, Subpart D”); COMMISSION REPORT, supra note 9, at 42–43 (assessing the “[r]isks and benefits of research involving children”). See also Loretta M. Kopelman, Children as Research Subjects: Moral Disputes, Regulatory Guidance, and Recent Court Decisions, 73 MOUNT SINAI J. MED. 596, 597 (2006) (arguing that as the courts have “reinforced the fact that the ‘best interest’ standard must be used for incompetent persons . . . . the failure to clarify the meaning of the pediatric regulations has sometimes misled generally risk-adverse institutions and dedicated investigators about what is permissible”); Michelle Oberman & Joel Frader, Dying Children and Medical Research: Access to Clinical Trials as Benefit and Burden, 29 AM. J.L. & MED. 301 (2003) (analyzing the intricacies of determining the “best interests” of the child in medical research).

¹¹. See 45 C.F.R. § 46.111(a)(3) (2015) (stating that the “IRB should take into account the purposes of the research and the setting in which the research will be conducted”). This section also prohibits the targeting of children for use in medical research studies. Id. § 46.111(b).


economically disadvantaged minorities by using them for participation in medical research studies for which there is no benefit.

Much of the work discussing the history and legacy of the Tuskegee Syphilis Study has focused on the violations of the Respect for Persons and Beneficence Principles. The discussion has rarely focused on the Justice Principle that prohibits exploitation. Exploitation is defined as the use of populations for research from which they will not benefit. My Article begins to fill this void by critically analyzing the current limitations of the Justice Principle to address structural and institutional racial biases in health care, which allow economically disadvantaged minorities to be exploited in medical research studies as they were in the Tuskegee Syphilis Study. Using research conducted on economically disadvantaged minority children as an example, my Article shows how even after the creation of the Justice Principle and the passage of the civil rights laws, structural and institutional racial biases remain and have led to the continued exploitation of economically disadvantaged minorities in medical research studies.

Part I of the Article provides a descriptive overview of the purpose and structure of medical research studies and examines the parameters

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15. Belmont Report, supra note 5, at 23,194. The Justice Principle also prohibits targeting. Targeting is the systematic selection of research subjects who are from vulnerable populations, such as racial minorities, children, and the economically disadvantaged, “because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.” Id. For a more detailed discussion concerning targeting, see Ruqaiijah Yearby, Missing the “Target”: Preventing the Unjust Inclusion of Vulnerable Children for Medical Research Studies, 42 AM. J.L. & MED. (forthcoming 2017) (discussing continued targeting in medical research involving children and proposing recommendations to prevent further targeting).

16. See Belmont Report, supra note 5, at 23,194 (“[T]he selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.”).
of the Justice Principle. Part II discusses the structural and institutional biases that prevent economically disadvantaged minority children from accessing health care and how this leads to their exploitation in medical research studies. Structural racial bias measures how non-race based factors, such as the delivery of health care based on ability to pay, indirectly affects economically disadvantaged minority children’s access to health care, whereas institutional racial bias focuses on the direct effects of institutional actions on economically disadvantaged minority children’s access to health care. In Part III, I propose several ways to put an end to exploitation, a violation of the Justice Principle in medical research studies.

Specifically, I suggest that the Justice Principle be redefined to include the Human Development Approach that requires researchers to provide a benefit to the population from which the research subjects originated that alleviates some of the populations’ underlying problems, such as lack of access to health care. This type of benefit is required because oftentimes either the researcher’s institution or the researcher’s actions have caused some of the underlying problems, such as lack of access to health care. To measure whether the research fulfills the Human Development Approach and provides a benefit that alleviates some of the underlying problems, researchers should be required to use the Vulnerability and Equity Impact Assessment (VEIA) tool, which I have created based on the Health Equity Impact Assessment tool. Using the VEIA, a newly created Board of Children would be responsible for approving all medical research studies seeking U.S. government funding that plan to use children. The Board would use the VEIA to determine if the research would exploit economically disadvantaged minority children in violation of the redefined Justice Principle.

Redefining the Justice Principle to include the Human Development Approach, implementing the VEIA, and creating a Board to review all

17. See Alex John London, Justice and the Human Development Approach to International Research, HASTINGS CTR. REP. 24, 32 (2005) (“[T]he minimalist approach does little to bring attention to the root causes of the developing world populations’ most pressing health needs. As a result, it perpetuates an ad hoc and piecemeal approach to the health needs of populations that already bear the greatest burden of disease and deprivation.”).

medical research studies using children will prevent economically disadvantaged minority children from being exploited in medical research studies for the benefit of an unworthy society.

I. MEDICAL RESEARCH STUDIES INVOLVING CHILDREN: THE STRUCTURE AND HISTORY

There are two types of medical research studies involving human subjects: non-therapeutic and therapeutic.19 Regardless of the type of medical research study, all studies using children entail risk of psychological and physical harm, as well as the possibility of stigma. In fact, countless children have suffered harm as a result of participating in medical research studies, often without any benefit to children.20 However, economically disadvantaged minority children have been and continue to be overrepresented in medical research studies that do not provide a benefit to economically disadvantaged minority children.21 This violates the Justice Principle.

The Justice Principle was created by incorporating social justice into scientific endeavors to protect populations from being exploited. In

19. Therapeutic or beneficial research “means that if the hypothesis of the research is correct, the subjects who participate should receive direct benefit from their participation.” Leonard H. Glantz, Research with Children, 24 AM. J.L. & MED. 213, 231 (1998). Non-therapeutic research, on the other hand, involves “no prospect of direct benefit to individual subjects, but [is] likely to yield generalizable knowledge about the subject’s disorder or condition.” Id.

20. Id. at 215–17 (discussing various historical experiments subjecting children to risk and harm); see also Susan Lederer & Michael Grodin, Historical Overview: Pediatric Experimentation, in Children as Research Subjects: Science, Ethics, and Law 3–20 (1994) (surveying the history of the use of children as medical research subjects). Children have been exploited in medical research studies for conditions that were not limited to children. Id. Moreover, many medical research studies conducted on children have no scientific value and are stigmatizing. See Solomon R. Benatar, Global Health and Justice: Re-Examining Our Values, 27 BIOETHICS 297, 301–02 (2013) (discussing how grant money could be distributed more effectively to reduce child mortality); Iain Chalmers & Paul Glasziu, Avoidable Waste in the Production and Reporting of Research Evidence, 374 LANCET 86, 86–89 (2009) (discussing wasteful and unnecessary research practices of the modern research landscape); WASHINGTON, supra note 2, at 271–96 (discussing scientific research that has targeted and stigmatized Black children); LAINIE FRIEDMAN ROSS, CHILDREN IN MEDICAL RESEARCH: ACCESS VERSUS PROTECTION 48, 50 (2006) (discussing the overrepresentation of Black children in various categories of research, including potentially stigmatizing research).

1979, the first discussion of the Justice Principle in medical research studies appeared in the United States *Belmont Report.* This report—mandated by the United States Congress—not only defined the Justice Principle, but also provided the framework for which to apply the principle to medical research studies. Since the codification of the Belmont Report in 1986, the Justice Principle has been applied to all medical research studies conducted by or funded by the federal government, except in emergency settings, as a means to protect vulnerable populations, such as economically disadvantaged minority children from being exploited.

A. Structure of Medical Research Studies Involving Human Subjects

A non-therapeutic medical research study is conducted to obtain generalizable scientific knowledge. This research is done to learn more “about the subjects’ disorder or condition, which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition.” An example of non-therapeutic research is the Kennedy Krieger lead study.

In the 1990s, Kennedy Krieger Institute researchers investigating cheap lead abatement techniques partnered with landlords to partially abate lead tainted housing in Baltimore, Maryland. In order to test the efficacy of the abatement procedures, the researchers—in collaboration with the landlords—ensured that only families with healthy children lived in the lead tainted housing by agreeing to pay for lead abate-
ment procedures if the landlords rented to families with young children. Although the information given to parents “implied that the study was protecting their children from lead damage and promised to inform parents of any hazards,” the study was non-therapeutic because it was conducted to find out more “about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition . . . .”

A therapeutic medical research study tests a vaccine, drug, or medical device for the treatment of a disease. An example of a therapeutic medical research study is the testing of HIV/AIDS drugs. There are five phases of therapeutic medical research studies: Phase 0, I, II, III, and IV. Using drug medical research studies as an example, each phase is discussed below.

In a Phase 0 drug study, research is conducted using at most ten people and involves the administration of small doses of an experimental drug over a short period of time to determine if there is any pharmacological effect. The purpose of the study is to evaluate whether there is any effect in humans before undertaking Phase I and II drug studies. Unlike Phase I drug studies, there is no therapeutic

30. Id. at 812.
32. Grimes, 782 A.2d at 811–12. There were many problems with the study. In fact, the researchers did not notify the parents of their children’s elevated lead levels or lead hot spots in the house. Id. at 825–31. As a result, many of the healthy children suffered exposure to lead. Id. Exposure to lead can cause inattention, irritability, hyperactivity, learning and reading delays, delayed growth and hearing loss, permanent brain damage, and even death. Lead Exposure in Children Affects Brain and Behavior, AM. ACAD. OF CHILD & ADOLESCENT PSYCHIATRY (Nov. 2012), http://www.aacap.org/aacap/fffprint/article_print.aspx?dn=Lead-Exposure-In-Children-Affects-Brain-And-Behavior-045 [https://perma.cc/L4AP-YNTN?type=image] [hereinafter Lead Exposure in Children].
33. 45 C.F.R. § 46.406(c) (2015).
34. See, e.g., id. § 46.405 (“HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject’s well-being . . . .”).
36. See id. (explaining that Phase 0 “involv[es] very limited human exposure to the drug, with no therapeutic or diagnostic goals”).
37. What are the Phases of Clinical Trials?, AM. CANCER SOC’Y, https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-
intent and little to no toxic effect in a Phase 0 drug study, which is primarily done for cancer drugs and therapies.  

In a Phase I drug study, research is conducted using a small number of subjects, less than 100 people, to obtain information regarding the safety and efficacy of the candidate drug on human subjects. Research that obtains information from several hundred subjects regarding the subjects’ immune system’s response, the efficacy of the drug on different populations, and the effect of different doses on the population is conducted in a Phase II drug study. 

After preliminary evidence has been obtained suggesting the effectiveness of a drug, a Phase III drug study is conducted “to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.” Researchers determine the efficacy of the drug for treating the disease by following anywhere from 300 to 3,000 subjects. This is the last Phase before the drug is marketed and distributed. Phase IV is the final step in drug studies. It includes “postmarket requirement and commitment studies . . . [to] gather additional information about a drug’s safety, efficacy, or optimal use.” The main difference between each phase is the purpose of the study and the benefit. In Phase 0, I, and II studies, the

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38. Id.; Clinical Trial Glossary, supra note 35.
40. FDA Clinical Research, supra note 39.
42. FDA Clinical Research, supra note 39.
43. Clinical Trial Glossary, supra note 35. See also Leslie Pickering Francis, Legitimate Expectations, Unreasonable Beliefs, and Legally Mandated Coverage of Experimental Therapy, 1 IND. HEALTH L. REV. 213, 228 (2004) (“Phase IV trials undertake continued collection of data after a new drug is given marketing approval based on data from earlier trials. The goal of Phase IV is to collect data on an ongoing basis as an approved therapy becomes employed in the general population of patients in need of treatment. Distribution of a therapy into the general population of patients, outside the research context, may reveal quite different aspects of the therapy’s risks and benefits.”).
goal is primarily the attainment of scientific knowledge, whereas in Phase III and IV studies, the goal is treatment.\textsuperscript{44}

Overall, regardless of the type of research being conducted, therapeutic or non-therapeutic, medical research studies offer the prospect of benefit to society. However, the Justice Principle requires that the population from which those serving as research subjects originate receive a benefit. Thus, if economically disadvantaged minority children serve as research subjects for medical research studies, whether therapeutic or non-therapeutic, all economically disadvantaged minority children should benefit from the studies either by receiving access to the drug or having the knowledge ascertained from the research used to assist them.

\section*{B. The Belmont Report}

In the early 1970s, the U.S. Senate Committee on Labor and Human Resources held hearings on some of America’s most egregious medical research studies, such as the Willowbrook study\textsuperscript{45} and the

\begin{footnotesize}
\footnote{44. See Francis, \textit{supra} note 43, at 227–28 (describing the purpose and scientific value underlying each phase).}

\footnote{45. For fifteen years (1956–1971) researchers conducted non-therapeutic medical research studies on children at the Willowbrook State School—an institutional facility for “mentally defective persons” on Staten Island, New York—to obtain scientific knowledge of “the natural history of hepatitis and the effects of gamma globulin in preventing or moderating its effects.” \textsc{Carl H. Coleman et al.}, \textit{The Ethics and Regulation of Research with Human Subjects} 39 (2005). Researchers infected healthy children—thus, the study was not to treat a disease from which the children suffered. Early in the study, the children were fed “extracts of stools from infected children, while later subjects received injections of more purified virus preparations.” \textit{Id.} The children were then gauged to determine the effects of gamma globulin in combating it. A hepatitis vaccine was developed due to this study. \textit{Id.} As a result of the study, healthy children were infected with a life-long debilitating disease so that researchers could develop a vaccine, which the infected children could never use, and as a result of the studies, the children were subjected to costly treatment for the rest of their lives. The researchers defended their research because there were outbreaks of hepatitis at the school, so they assumed that the children would eventually acquire the disease. \textit{Id.} At the time of the study, several major medical journals (the \textit{Journal of the American Medical Association} and the \textit{New England Journal of Medicine}) published the results of the study, commending the researchers for their use of vulnerable children and asserting that the children actually benefited “from being infected under carefully controlled research conditions and receiving expert attention.” \textit{Id.} However, some researchers and scholars disagreed, alluding to the fact that healthy children were fed stool extracts and received no benefit from the study because there is no cure for hepatitis. Furthermore, many argued that the choice to use that population seems to have been driven by the convenience of the children, not any lofty moral intentions. \textit{See id.} at 40 (describing coercive tactics used by institutional directors to secure the consent by parents for their children’s participation in the study).}
\end{footnotesize}
Tuskegee Syphilis study. As a result of the hearings, Congress created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Commission) and imposed a moratorium on research conducted or supported by the U.S. Department of Health and Human Services (HHS) until adequate protections for research subjects were developed.

The Belmont Report was an outgrowth of the Commission’s deliberations regarding ethical protections and a 1976 conference at the Smithsonian Institution’s Belmont Conference Center. In the Belmont Report, the Commission selected Justice as one of the three fundamental ethical principles to address the exploitation of vulnerable groups for medical research studies. The Commission noted that in the United States the burden of participating in medical research studies was borne principally by the economically disadvantaged while the rich enjoyed

46. The Tuskegee Syphilis Study, conducted from 1932 through 1972, denied standard access to treatment to economically disadvantaged African-American men. See Belmont Report, supra note 5, at 23,194 (describing the recruitment of “disadvantaged, rural black men” to the Tuskegee study); Jones, supra note 2, at 206–19 (discussing the evolution of the Tuskegee Study).

47. The Commission was composed of eleven members appointed by the Secretary of HHS. National Research Act of 1974, Pub. L. No. 93-348, § 201(a), 88 Stat. 342, 348 (codified as amended in scattered sections of 42 U.S.C). The National Research Act advised the Secretary of HHS to choose the members of the Commission from “individuals distinguished in the fields of medicine, law, ethics, theology, philosophy, humanities, the biological, physical, behavioral, and social sciences, health administration, government, and public affairs.” Id. § 201(b)(1). Five of the members of the Commission had to be individuals “engaged in biomedical or behavioral research involving human subjects.” Id. Members of the Commission included: Dorothy I. Height, President, National Council of Negro Women, Inc., Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at San Francisco, and Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center, and others. Belmont Report, supra note 5, at 23,192.

48. Prior to 1980, the U.S. Department of Health and Human Services (HHS) was called the U.S. Department of Health, Education, and Welfare. Department of Education Organization Act, Pub. L. No. 96-88 § 509(a), 93 Stat. 668, 695 (1979) (codified at 20 U.S.C. § 3508 (2006)). However, to avoid confusion when discussing events before and after the name change, I refer to the agency only as HHS.


50. Belmont Report, supra note 5, at 23,192.

51. Id. at 23,194. The two other principles were Respect for Persons and Beneficence. Id.
the benefits, as evidenced by the Tuskegee Syphilis Study.\textsuperscript{52} To address this inequitable burdening of the poor and minorities, the Report included the Justice Principle based on John’s Rawls Egalitarian theory as refined by Tom Beauchamp and James Childress.

According to John Rawls, the Justice Principle encompasses fairness and equity, which “are not subject to political bargaining or to the calculus of social interests.”\textsuperscript{53} Unlike Utilitarianism that allows for harm for the benefit of the greater good, Rawls’ notes that “justice denies that the loss of freedom for some is made right by a greater good shared by others. It does not allow that the sacrifices imposed on a few are outweighed by the larger sum of advantages enjoyed by many.”\textsuperscript{54} Adding to John Rawls’ theory, Tom Beauchamp and James Childress submit that Egalitarianism imposes a “positive societal obligation to reduce or eliminate barriers that prevent fair equality of opportunity, an obligation that extends to programs to correct or compensate for various disadvantages.”\textsuperscript{55} Based on this refined Egalitarian theory of Justice, the Commission used the Justice Principle to answer the questions: “Who ought to receive the benefits of research and bear its burdens?”\textsuperscript{56} Specifically, the Commission defined what is just and unjust in the use of research subjects.

In selecting research subjects, the Justice Principle requires that researchers ensure that disadvantaged groups such as minorities, women, children, the institutionalized mentally infirm, prisoners, and the economically disadvantaged\textsuperscript{57} are not “being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.”\textsuperscript{58} The Commission reasoned that:

[W]henever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve

\textsuperscript{52} Id.

\textsuperscript{53} John Rawls, A Theory of Justice 3–4 (Harvard Univ. Press rev. ed., 1999). Widely considered as the most significant contribution to law and philosophy, John Rawls created Egalitarianism as an alternative concept to the Utilitarian theory of justice. See id. at xvii–xviii (presenting an “alternative systematic account of justice”).

\textsuperscript{54} Id. at 3.

\textsuperscript{55} Tom Beauchamp & James Childress, Principles of Biomedical Ethics 248 (6th ed. 2009).

\textsuperscript{56} Belmont Report, supra note 5, at 23,194.

\textsuperscript{57} Id. at 23,194, 23,196–97.

\textsuperscript{58} Id. at 23,194.
persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.59

According to the Commission, an injustice occurs during medical research when a benefit is denied to a person without good reason or a burden is unduly imposed on a person, whereas Justice requires “that equals ought to be treated equally.”60 As applied to medical research, “the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects” on two levels: individual and social.61 On the individual level, researchers should include the disadvantaged in potentially beneficial research that is usually reserved for the rich,62 instead of using them for non-therapeutic and dangerous medical research studies. On the social level, researchers must draw a distinction “between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons.”63 The Belmont Report noted that it was not fair for the economically disadvantaged, who rely on public funds for health care, to be considered as preferred research subjects for publicly funded research because of their need to access health care.64 Thus, there is an order of preference in the selection of research subjects, such that researchers should use the rich before the economically disadvantaged, the majority before minorities, and adults before children. Moreover, there is a requirement that if a population serves as research subjects for the studies, that population should receive a benefit from the research.65

On an individual level, the Justice Principle requires inclusion of vulnerable groups for potentially beneficial research,66 while on a social
level this inclusion must be balanced to protect vulnerable groups from being overburdened. Nevertheless, even after researchers balance the individual and social level requirements of the Justice Principle, the use of certain classes of people for research may be unjust because of “social, racial, sexual and cultural biases institutionalized in society” that place a class of people in a vulnerable and compromised position, easily manipulated into participation in medical research studies, without any benefit to the population from which the subject originated.

For example, over three decades of empirical research studies show that racial bias institutionalized in society prevents many African Americans from receiving a quality education, obtaining jobs, and accessing housing in safe, diverse, and environmentally-friendly neighborhoods.

67. Id.
68. Id.
Studies show that African Americans seeking employment have a harder time obtaining employment because non-African American managers tend to hire more Caucasians.\textsuperscript{70} Also, African Americans with non-Caucasian names receive fifty percent less callbacks than African Americans with Caucasian sounding names.\textsuperscript{71} As a result, many African Americans are more likely to be unemployed or employed with no health insurance. Lacking health insurance or money to pay for health care, African Americans are left in a compromised position and easily manipulated into participating in medical research studies to obtain access to health care. Consequently, even if researchers fairly select African Americans as research subjects, these institutional racial biases that prevent them from accessing health care make their use as research subjects a violation of the Justice Principle because they will not receive a benefit even if the research leads to a treatment, since they do not have access to health care.\textsuperscript{72}

Beginning in the 1980s, the \textit{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).\textsuperscript{73} In fact, not only did the Common Rule make the Justice Principle law, but it also explicitly defined the groups protected by the Justice Principle as
vulnerable populations that shall not be exploited. Vulnerable populations include minorities, children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons. The Common Rule generally governs all research studies conducted by or funded by the federal government.

C. The Common Rule

Institutions receiving federal funding to conduct medical research studies must enter into a contractual agreement with the federal government, called an assurance, asserting that they will comply with the Common Rule. 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. The Office for Human Research Protections (OHRP), a federal agency housed within HHS, is responsible for ensuring that institutions comply with their assurances. To fulfill this task, OHRP may request additional information in writing, conduct telephone interviews, or conduct site visits. These visits can be random or in response to allegations of noncompliance with the Common Rule.

76. Coleman et al., supra note 45, at 107.
77. There are several types of assurances. See generally Lori A. Alvino, Who’s Watching the Watchdogs? Responding to the Erosion of Research Ethics by Enforcing Promises, 103 Colum. L. Rev. 893, 899–900 (2003) (discussing Single Project Assurances, Multiple Project Assurances, and Cooperative Project Assurances, and how those assurances must be replaced by Federal Wide Assurances when they expire).
78. 45 C.F.R. § 46.103 (2015).
79. Id.
80. Id.
81. Coleman et al., supra note 45, at 136–37; Memorandum from Director, OHRP, to OHRP Staff, Regarding Compliance Oversight Procedures (Dec. 4, 2000), in The Ethics and Regulations of Research with Human Subjects 138, 141 (2005) [hereinafter OHRP Memorandum].
82. Coleman et al., supra note 45, at 136–37. For government funded medical research studies in which there has been an allegation of noncompliance, OHRP initiates an investigation. Id. at 140–41 (detailing the sequence of events in compliance investigations).
When reviewing allegations of noncompliance, OHRP grants the institution an opportunity to refute the allegations.\textsuperscript{83} Once additional information is obtained, OHRP determines whether the institution has violated the law.\textsuperscript{84} OHRP issues corrective action for instances of noncompliance, which is in “the best interests of human research subjects, and to the extent possible, the institution, the research community, and HHS.”\textsuperscript{85} Corrective action may include restriction or withdrawal of approval for an institution’s assurance and suspension or permanent removal from participation in specific projects.\textsuperscript{86} Information regarding allegations and findings of noncompliance can be found on OHRP’s website.\textsuperscript{87}

OHRP is responsible for reviewing compliance at the institutional level.\textsuperscript{88} Every institution that has an assurance with OHRP is responsible for ensuring that individual medical research studies conducted by

\begin{footnotes}
\footnotetext[83]{OHRP Memorandum, \textit{supra} note 81, at 139.}
\footnotetext[84]{Id. at 141.}
\footnotetext[85]{Id.}
\footnotetext[86]{Id. at 140. Many, including the former Secretary of HHS, have argued that OHRP has failed to issue meaningful sanctions. \textit{See} L. Song Richardson, \textit{When Human Experimentation Is Criminal}, 99 \textit{J. Crim. L. & Criminology} 89, 124–26 (2009) (discussing how institutions that are supposed to police research fail to deter unethical conduct because of their reliance on self-policing); Donna Shalala, \textit{Protecting Research Subjects—What Must Be Done}, 343 \textit{New Eng. J. Med.} 808 (2000) (arguing for a strengthening of the regulatory system protecting human research subjects). One form of sanction the OHRP imposes is posting a letter of violation on its website. OHRP Memorandum, \textit{supra} note 81, at 141. \textit{See generally} OHRP \textit{Determination Letters}, HHS.gov, http://www.hhs.gov/ohrp/compliance-and-reporting/determination-letters/index.html [https://perma.cc/9C4X-KR8V] (exhibiting a searchable database of OHRP determination letters). However, in the past when the public pressure has become too much, some institutions have voluntarily stopped the research studies, while others have continued the research studies. \textit{See generally} David B. Resnik, \textit{Research Ethics Timeline}, Nat’l Insts. Of Health, http://www.niehs.nih.gov/research/resources/bioethics/timeline/ [https://perma.cc/LX68-JKNP] (last updated Feb. 13, 2017) (identifying 1972 as the year “the national media and Congress [began] focusing] on unethical research practices with human subjects, including the Tuskegee study”). Yet, this is an erratic outcome that simply depends on how much media attention the study received. \textit{See id.} (providing a timeline that suggests unethical research studies have persisted despite greater national attention and media scrutiny).
those affiliated with the institution comply with the Common Rule.  

To accomplish this task, all institutions and federal agencies that enter into an assurance with OHRP have an Institutional Review Board (IRB). There are an estimated 3,000 to 5,000 IRBs, which serve as the main protection for vulnerable populations in medical research studies.

Before researchers can be funded by the United States government or conduct medical research studies using human subjects in the United States, they must submit a research protocol to their IRB. A complete research protocol includes a statement of compliance with the ethical principles, including the Justice Principle. The IRB reviews all written research protocols in application for medical research studies using human subjects to ensure that the proposed studies are ethical. If the IRB finds that the research protocol is ethical, 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.

In terms of the Justice Principle, the IRB is required to ensure that the “[r]isks to subjects are minimized: (i) [b]y using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk,” and the “[s]election of subjects is equitable.” This section prohibits the exploitation of vulnerable populations, which is the use of vulnerable populations for medical research studies that vulnerable populations will not benefit from, while the rest of society act as free riders reaping the benefits without sacrifice. If

93. Id. § 46.103(b)(1).
94. Id.
95. Id. § 46.103(a).
98. Id. § 46.111(a)(3) (emphasis added).
99. Id.
the IRB fails to ensure that vulnerable populations are not exploited, then OHRP may issue a corrective action. 100

In 1990, there was a paradigm shift in the use of the Justice Principle, which has allowed researchers to exploit economically disadvantaged minority children. 101 Specifically, instead of using the Justice Principle to protect economically disadvantaged minority children from exploitation, now researchers use the Justice Principle to include economically disadvantaged minority children in medical research studies that not only unnecessarily exposing them to risks, causing harm, but also failed to provide a benefit to the population from which they originated. 102

II. Inclusion, Exploitation, and Bias

In the 1990s, Congress passed laws to ensure that a number of populations (women, minorities, children, and the economically disadvantaged), who were perceived as being left out of medical research, were included in medical research studies. 103 Participating in medical research studies provides economically disadvantaged minority children, who are research subjects, with access to health care during the study. 104 However, because of structural and institutional racial biases that limit access to health care to those who can pay, economically disadvantaged minority children’s access to health care

100. OHRP Memorandum, supra note 81, at 139–40.


102. See generally id. at 51 (2002) (discussing the tensions in the Justice Principle between including vulnerable populations and excluding vulnerable populations); Levine, supra note 1, at 116 (discussing how research involving sick children presents particularly difficult situations for investigators).


ends once the medical research study ends. As a result, economically disadvantaged minority children are being exploited in medical research studies, since the population from which they originate will not benefit from the research because they lack access to health care and the research unnecessarily exposes them to risk. Inclusion without a benefit is exploitation, which is a violation of the Justice Principle.

A. Inclusion

The Justice Principle was only in effect for a few years when the federal government shifted its definition from protection of vulnerable populations to inclusion of vulnerable populations to promote greater access to medical research studies. This shift in meaning was a result of the Human Immunodeficiency Virus and the Acquired Immune Deficiency Syndrome (HIV/AIDS) epidemic and the perceived lack of participation of economically disadvantaged minority children in medical research studies.

As Carol Levine notes, medical research studies became synonymous with treatment during the HIV/AIDS epidemic. Due to the HIV/AIDS crisis, people were dying with no hope for treatment. New HIV/AIDS drugs and therapies were being tested in medical research studies, but not available to the general public. Thus, HIV/AIDS medical research was viewed as "cutting-edge medical treatment" not "experimental research" that could cause serious harm. Consequently, some HIV/AIDS activists began to argue that medical research "served as an important means of access to otherwise unobtainable and theoretically helpful new therapies."

Because in the 1990s the HIV/AIDS disease disproportionately affected vulnerable populations allegedly protected from the harms of medical research (women, minorities, and children), these vulnerable

105. See Washington, supra note 2, at 271–98 (discussing research targeting black children).
106. Ross, supra note 20, at 24.
107. Yearby, supra note 15, at 23. It was also a result of the belief that children were therapeutic orphans. Id.
108. Levine, supra note 1, at 108–09 (describing demands by individuals suffering from AIDS to participate in clinical drug trials with the hope of receiving a benefit).
110. Id. at 271.
populations, civil rights organizations, physicians, and researchers advocated for vulnerable populations’ right to participate in medical research studies to gain access to potentially life-saving treatment. The argument for the need for inclusion was further bolstered by media reports that minorities and children lacked access to HIV/AIDS drug studies.

For example, using National Institutes of Health (NIH) documents, a reporter noted in a front page Los Angeles Times article that African Americans, Latinos, and groups disproportionately afflicted with HIV/AIDS were significantly underrepresented in federally funded HIV/AIDS medical research studies. Advocates of inclusion also argued that children with HIV/AIDS in the United States did not receive AZT until three years after adults gained access to AZT because children were denied participation in medical research studies as a result of the Justice Principle.

This theory of inclusion is based on an incorrect assumption that economically disadvantaged minority children were not participating in medical research studies, including those related to HIV/AIDS. However, as discussed below, even once the Justice Principle was adopted in 1979, economically disadvantaged minority children were participating in medical research studies.

B. Using Inclusion to Exploit

In the late 1980s, researchers in Los Angeles gave healthy African American infants five hundred times the approved dose of an experimental measles vaccine, which had already sickened and killed children in Senegal, Mexico, and Guinea-Bissau. This medical research study failed to provide any benefit to the population from which the subjects originated and unnecessarily exposed children to a risk researchers knew was harmful.

As discussed in Section I.A., in the 1990s, Kennedy Krieger Institute researchers investigating cheaper lead abate techniques partnered with landlords to partially abate lead tainted housing in Baltimore.

112. Levine, supra note 1, at 109.
114. Id. at 63.
115. Washington, supra note 2, at 295.
116. See id. (explaining that the vaccine was administered after the researches knew it would serve no benefit to the children because of the prior experimental deaths in other countries).
In order to test the efficacy of the abatement procedures, the researchers in collaboration with the landlords ensured that only families with healthy children lived in the lead tainted housing by agreeing to pay for lead abatement procedures if the landlords rented to families with young children. Due to the socioeconomic status and racial makeup of the neighborhood, the young children participating in the study were all economically disadvantaged minorities. Even though the information given to parents “implied that the study was protecting their children from lead damage and promised to inform parents of any hazards,” such as abnormal tests showing high lead levels, the study was non-therapeutic because it provided no benefit to the participants. In fact, contrary to their promise, the researchers did not notify the parents of their children’s elevated lead levels or lead hot spots in the house, so that the parents could protect their children from lead exposure. As a result, many of the healthy children suffered exposure to lead, which can cause inattention, irritability, hyperactivity, learning and reading delays, delayed growth and hearing loss, permanent brain damage, and even death. Thus, this study did not provide a benefit to the population from which the subjects originated and unnecessarily exposed children to a risk researchers knew was harmful.

From 1992 to 1997, researchers at the Columbia University’s Lowenstein Center for the Study and Prevention of Childhood Disruptive Behavior Disorders and New York City’s New York State Psychiatric Institute conducted research to try to show a link between genetics and violence, including only African American and Latino children as subjects. The researchers administered fenfluramine to 126 boys between the ages of six and ten, even though the drug had already been shown to cause heart-valve damages, pulmonary hypertension (a life threatening form of high blood pressure), brain damage, and death in adults, unnecessarily exposing children to a risk researchers knew was harmful.

As a result of their inclusion in the study, the children were exposed to the same risks of physical harm the adults suffered who were pre-

118. Id. at 811–12.
119. Id. at 812.
120. Washington, supra note 2, at 292.
121. Grimes, 782 A.2d at 811–12 n.2.
122. Id. at 825.
123. Lead Exposure in Children, supra note 32.
125. Id. at 272–75.
viously administered fenfluramine, including but not limited to “an-
xiety, fatigue, headache, lightheadedness, difficulty concentrating, vi-
sual impairment, diarrhea, and nausea.”126 No generalizable knowledge
was obtained from this study because the premise of the research that
genetics was linked with violence had been disproven by over a century
of research, and thus, the research was not using procedures that were
consistent with sound research design.127 Furthermore, the researchers’
use of only minorities in the study, even though Caucasians also commit
acts of violence, sent the message that minorities are more violent than
Caucasians and thus must be studied.128 Hence, the research exploited
the children for a medical research study that unnecessarily exposed
children to a risk researchers knew was harmful, unfairly labeled them
as more violent than Caucasians, and provided no generalizable knowl-
dge because the procedures that were used were not consistent with
sound research design.

These studies are not outliers. In fact, Harriet Washington’s sem-
inal book, Medical Apartheid, shows that economically disadvantaged
minority children have still been exploited in medical research studies
after the creation and implementation of the Justice Principle.129 Even
when included in medical research studies conducted to find drugs for
use in children, many economically disadvantaged children are still used
for medical research studies that unnecessarily exposed children to a
risk researchers knew was harmful and provided no benefit for the pop-
ulation from which they originate.

For instance, for thirteen years (1988–2001), Illinois, Louisiana,
Maryland, New York, North Carolina, Colorado, and Texas enrolled
foster children between the age of three months to nineteen years old
in Phase I and II drug studies for the treatment of the HIV/AIDS.130
The majority of the foster children used for the study were economically
disadvantaged minorities.131 The studies were conducted to determine

126. Id. at 275.
127. Id. at 275–76.
128. Id. at 277–78.
129. Id. at 236–37, 284, 294–95.
130. John Solomon, Government Tested AIDS Drugs on Foster Kids, NBC News
(May 4, 2005, 5:30 PM), http://www.nbcnews.com/id/7736157/ns/health-
aids/t/government-tested-aids-drugs-foster-kids/#.WKe29RLaeT8 [https://
perma.cc/6UQG-NH45]. The medical research tested various different drugs
including protease inhibitors, Ritonavir therapy, and the live-attenuated
Varicella vaccine. See Letter from Karen Cooper, Compliance Oversight
Coordinator, Office for Human Research Prots., to Harvey R. Colten, Vice
President and Senior Assoc. Dean, Columbia Univ. Medical Ctr., and Laura
L. Forese, Vice President and Chief Medical Officer, N.Y. Presbyterian Hosp.
(May 23, 2005) (on file with author) (describing findings of the OHRP review).
131. Solomon, supra note 130.
the drug toxicity and adverse side effects of drugs that had not been shown to be safe in adults. Advocates of the research have argued that the inclusion of these children in the research benefited economically disadvantaged minority children by increasing their access to new and effective HIV/AIDS drugs. Notwithstanding this assertion, OHRP investigated the use of economically disadvantaged minority children in these HIV/AIDS drug studies and found that their use in many of these studies was inequitable and violated the Justice Principle.

Seventeen years after the HIV/AIDS drugs studies started, OHRP issued a letter to the head of the IRB at Columbia University Medical Center, noting that some of the HIV/AIDS drug studies conducted at Columbia University Medical Center violated the law. Specifically, the IRB approved research protocols in which researchers had inequitably used economically disadvantaged minority children in foster care to participate in the studies. In 2006, OHRP sent letters of violation to eighteen other universities conducting HIV/AIDS drug studies. Each

132. Id.

133. See Levine, supra note 1, at 117 (noting that “[b]ecause many of the potential child subjects for HIV/AIDS research are in foster care, their opportunities for participation have been severely limited by the lack of state or agency policies and the reluctance of agency officials to approve the entry of children into trials”).

134. Letter from Karen Cooper, supra note 130. There was also an issue of targeting the children because of their manipulability and compromised position. See Yearby, supra note 15, at 30 n.155 (“In addition to this subjection of economically disadvantaged minority children to hazardous drug trials, some researchers failed to obtain proper consent from participa[nts] in the trials. There were two common practices that violated the informed consent laws. First, five children participating in the New York drug trials between five and ten years of age were asked to sign consent forms once they were told of the risks and benefits. Second, many of the researchers failed to obtain consent from an authorized person, such as an independent advocate, for each child. The only consent that researchers obtained for participating foster children were blanket consents from child welfare agencies. None of the 200 Illinois foster children were appointed independent monitors 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, monitors were only appointed to one-third of the 465 foster children participating in the medical research studies.”) (quoting Solomon, supra note 130).

135. Letter from Karen Cooper, supra note 130.

136. See, e.g., Letter from Julia Gorey, Div. of Compliance Oversight, Office of Human Research Protections, to Ronald R. Peterson, President of Johns Hopkins/Johns Hopkins Health Sys. (Feb. 17, 2006) (on file with author) (explaining the indicators of the university’s “noncompliance with [HHS] regulations for the protection of human research subjects,” with reference to certain research projects). The following institutions received similar letters determining that they had selected foster children inequitably: Bellevue
letter noted that the universities had used economically disadvantaged minority foster children in violation of the Justice Principle and 45 C.F.R. § 46.111(a)(3).\textsuperscript{137}

Nevertheless, OHRP did not put an end to the studies, did not impose any sanctions, and its findings failed to directly address the actions of the researchers who violated the Justice Principle.\textsuperscript{138} Consequently, the researchers who conducted the studies were able to publish their findings in main medical journals without repercussion. In issuing its findings, OHRP did not even explain why they found that the studies using economically disadvantaged minority children as research subjects violated the Justice Principle, but I suggest several reasons.

First, it was not clear at the time of the studies that minority foster children were one of the populations suffering from HIV/AIDS.\textsuperscript{139} Thus, participation in the studies was not a benefit to the population. In fact, the minority foster children included in the HIV/AIDS drug studies were not even adequately tested for HIV/AIDS.\textsuperscript{140} 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 infected with HIV/AIDS.\textsuperscript{141} Thus, Hospital Center, Bronx-Lebanon Hospital Center, Children’s Hospital Association, Children’s Hospital of King’s Daughters, Children’s Hospital of Philadelphia, Children’s Hospital and Research Center at Oakland, Children’s Hospital and Regional Medical Center, Columbia University Medical Center, Cook County Bureau of Health Services, Drexel University College of Medicine, Duke University School of Medicine, SUNY Health Science Center, Stony Brook, SUNY Upstate Medical University, Universidad Central del Caribe, University of Chicago, University of Maryland Baltimore School of Medicine, University of Medicine and Dentistry of New Jersey, and University of Miami. See Letters from the Office for Human Research Prots. (on file with author).

\textsuperscript{137} See supra note 136 and accompanying text.

\textsuperscript{138} Id.


\textsuperscript{140} Solomon, supra note 130; see also Sharav, supra note 139 (explaining that a false positive is possible in young infants with HIV-positive mothers because “in the uninfected infant, passively acquired maternal IgG antibodies disappear on average in 7 to 10 months, but may occasionally persist until 18 months. Therefore, a positive HIV antibody test in the young infant merely confirms maternal HIV infection but is not diagnostic for HIV infection specific to the infant.” (citing New York State Department of Health (DOH), Clinical Care of Adolescents and Children with HIV Infection: HIV Testing and Diagnosis, HIVDENT, http://www.hivdent.org/__pediatrics__/dohdoh11/1section1iii.htm [https://perma.cc/YJP6-23YY] (last visited Apr. 27, 2017))).

\textsuperscript{141} Sharav, supra note 139.
it can be argued that the children were selected simply “because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.”

Second, the children were public wards and according to the Justice Principle, researchers are not allowed to use the economically disadvantaged, who rely on public funds for health care, to be used as research subjects for publicly funded research because they are already overburdened and unlikely to benefit as a population from the research.

Third, the healthy children were unnecessarily “exposed . . . to the 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.” The drugs tested were failed cancer drugs that had severe side effects including “rashes, vomiting and sharp drops in infection-fighting blood cells,” and death. Hence, yet again, healthy minority children were subjected to unnecessary risks that researchers knew were harmful.

The dangers of participation in these studies for healthy children are best illustrated by an Illinois study of dapsone, a drug to prevent AIDS-related pneumonia. “Researchers reported that 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 “[a]t 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 dosage. They said the deaths didn’t appear to be ‘directly attributable’ to dapsone but nonetheless were ‘disturbing.’”

Finally, research shows that not only did some of these healthy children experience long-term disability or die as a result of their participation in these studies, but also it shows that many economically disadvantaged minority children in the United States still do not have

142. Belmont Report, supra note 5, at 23,194.
143. Id. at 23,196–97.
144. Solomon, supra note 130.
145. Id.
146. Id.
147. Id.
148. Id. (emphasis added). This was not the only clinical trial in which death was a side effect of the drugs. “In one study, researchers reported a ‘disturbing’ higher death rate among children who took higher doses of a drug. That study was unable to determine a safe and effective dosage.” Id.
149. Id.
access to this medicine. The studies did not provide a benefit to economically disadvantaged children because structural and institutional racial biases limit their access to health care and medicine.

C. Bias in Health Care

Structural racial bias operates at the societal level, denying some groups access to the resources of society, while privileging other groups.

“Institutional [racial] bias operates through organizational structures and establishes ‘separate and independent’ barriers through the neutral denial of access to quality health care that results from the normal operations of the institutions in a society.”

Although most research on structural and institutional racial biases within the health care system focuses on adults, it is clear that when these adults have children, the biases also impact their children’s access to health care. I will discuss how these biases that affect adults impact their children and where available, I will discuss research that has directly focused on children.

1. Structural Racial Bias

“Structural racial bias is a result of ‘power relationships that exist between racial and socioeconomic groups, where [one] dominant group[] holds power over [the] other[] [group] and use[s] that power to secure


152. Ruqaiijah Yearby, Racial Disparities in Health Status and Accessing Health Care, in DEBATES ON U.S. HEALTHCARE 78, 83 (Jennie Jacobs Kronenfeld et al. eds., 2012).

153. Children’s Health Disparities are not often studied, which is why Ivor Braden Horn of the Children’s National Medical Center and Anne C. Beal of The Commonwealth Fund wrote an article calling for the framing of a research agenda for studying child health disparities. See generally Ivor B. Horn & Anne C. Beal, Child Health Disparities: Framing a Research Agenda, 4 AMBULATORY PEDIATRICS 269 (2004) (providing a framework for research on child health care disparities).
material and social resources such as income [and] wealth.154 The dominant group remains in power “because [its] position in society en-ables [it to retain power] despite the will or aims of [the groups it] has power over.”155 In health care, 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.”156 The privileged obtain access because they are able to afford health insurance or pay for health care not covered by insurance. Those without privi-lege, such as minorities and the economically disadvantaged, have limi-ted access to health care because they do not have health insurance or they cannot afford to pay for health care.157 For instance, “African Americans and Hispanics are more likely than Caucasians to work in low-wage jobs, and tend to have reduced access to employer-sponsored coverage relative to their higher-wage counterparts.”158 This directly affects the health care of African American and Hispanic children.

For example, most union-represented housekeeping, maintenance, and other service workers at the Johns Hopkins Hospital are paid under $14.91 per hour, leaving them below the poverty level.159 As a result of the low pay, their children are uninsured or on Medicaid because they cannot afford to purchase Hopkins health insurance.160 Consequently, minority children and adults are more likely than Caucasians to be uninsured. This has not changed 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 dis-advantaged adults (from 35% to 24%) and Hispanics (from 36% to 23%).161 In 2014, thirty-three million people (10.4%) were without

155. Id.
156. Id.
157. Id. at 80.
158. Id. at 83.
160. Id.
health insurance.\textsuperscript{162} 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.\textsuperscript{163} 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, DC and thirty-one states have expanded Medicaid to cover economically disadvantaged adults. However, in the nineteen 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.\textsuperscript{164} 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.\textsuperscript{165}

More than sixty percent of the economically disadvantaged, who are in a family with a worker, remain uninsured because of the failure to expand Medicaid.\textsuperscript{166} They work in part-time jobs, jobs for employers with less than fifty employees (so not covered by the ACA penalties), or jobs that do not provide health insurance like those in the agriculture and service industries.\textsuperscript{167} Because minorities are more likely to work in these industries and live in families with lower incomes than Caucasians, they disproportionately remain uninsured due to the failure to

\begin{footnotes}

\textsuperscript{163} \textit{Id.}

\textsuperscript{164} \textit{Id.}


\textsuperscript{166} \textit{Id.} at 4.

\textsuperscript{167} \textit{Id.}
\end{footnotes}
expand Medicaid. In fact, minorities make up over half of the uninsured, while only accounting for forty percent of the U.S. population. This affects children as well.

Before the ACA, an estimated eight million children were uninsured. The three states with the highest number of uninsured children were Texas (21.4%), Florida (19.2%), and New Mexico (15.5%). Since the passage of the ACA, an estimated five million children remain uninsured. Although the federal government partners with states under Medicaid and the Children’s Health Insurance Plan to provide health insurance for nearly forty percent of all economically disadvantaged children, minority children are still more likely to be uninsured than Caucasian children. These uninsured children are more likely to live in low-income families and almost a quarter of them are in fair or poor health.

Moreover, earlier studies have shown that “uninsured children are also more likely . . . to have gone without needed medical, dental, or other health care . . . . [and they are] more likely to rely on the emergency room as their usual source of care.” Lack of insurance also results in lack of access to prescription medicine. A poignant example of how structural racial bias affects economically disadvantaged children access to health care is the Deamonte Driver story.

Deamonte Driver, an African American male youth, died of a toothache because he did not have health insurance and so he never received a routine $80 tooth extraction that may have saved him. Deamonte

168. Id. at 2.
171. Id.
173. Id. at 6.
175. Id. at 3.
176. Id.
Driver’s family was no different than most working poor families. His mother worked several jobs, but none provided insurance, or paid enough for the family to buy insurance.\footnote{178} Deamonte was covered under Medicaid, which covers oral health services.\footnote{179} However, he never received the dental care he needed because there was a shortage of dentists willing to treat Medicaid patients or those who cannot afford to pay for health care.\footnote{180} By the time his mother was able to locate a dentist willing to take Medicaid, Deamonte was no longer covered by Medicaid and thus did not receive treatment.\footnote{181}

Lacking health insurance, Deamonte received all of his care in an emergency room or hospital.\footnote{182} Instead of a tooth extraction, his care included two brain surgeries, six weeks of hospitalization, and physical and occupational therapy, totaling $250,000.\footnote{183} On his last day, Deamonte played cards and watched a show on television with his mother.\footnote{184} When he called her later that evening, Deamonte said, “Make sure you pray before you go to sleep.”\footnote{185} The next morning, Deamonte was dead from a brain infection caused by the spread of the bacteria from the abscess in his mouth.\footnote{186} Deamonte did not have to die; he was only a twelve-year-old boy with a cavity. He died because health care in the United States is provided based on ability to pay, not medical need. Deamonte’s death is not an outlier. In fact, a research study conducted by Johns Hopkins Children’s Center found that uninsured children faced a sixty percent increased risk of dying than insured children.\footnote{187}

Even if economically disadvantaged minority children are covered by Medicaid, this does not guarantee them access to medical and dental

\footnote{178} Id.
\footnote{179} Id.
\footnote{180} Id.
\footnote{181} Id.
\footnote{182} Id.
\footnote{183} Id.
\footnote{184} Id.
\footnote{185} Id.
\footnote{186} Id.
care. Research shows that Medicaid patients have a difficult time accessing health care because Medicaid reimbursement rates are so low.\textsuperscript{188} In fact, numerous states, including California, Florida, Illinois, Massachusetts, and Texas, have been sued for failing to provide children with early and periodic screening, diagnosis, and treatment.\textsuperscript{189} Moreover, when minorities and the economically disadvantaged obtain private 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.

According to a Commonwealth Fund report, in 2014 over thirty-one million people were underinsured, about twenty-three percent of those with year-round health insurance.\textsuperscript{190} Of the underinsurance, forty-four percent reported forgoing care because of the cost, and fifty-one percent reported having problems paying medical bills or debts, totaling $4,000 or more.\textsuperscript{191} People with low incomes under 200% of the federal poverty line accounted for sixty-one percent of underinsured adults in the U.S.\textsuperscript{192} By 2015, the U.S. Census bureau reported that 46.2 million people (14.7%) were in poverty in the United States.\textsuperscript{193} 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.\textsuperscript{194} The rate of poverty for African Americans was 25.8% and 23.2% for Hispanics compared to 11.6% for Caucasians.\textsuperscript{195}

\begin{footnotesize}
\begin{enumerate}
\item[190.] Sara R. Collins et al., \textit{The Commonwealth Fund, The Problem of Underinsurance and How Rising Deductibles Will Make It Worse 1} (2015).
\item[191.] Id.
\item[192.] Id. at 15.
\item[195.] Carmen DeNavas-Walt et al., U.S. CENSUS BUREAU, \textit{Income, Poverty, and Health Insurance Coverage in the United States:}
\end{enumerate}
\end{footnotesize}
Adding insult to injury, the wealthy, who predominantly have health insurance, receive discounts on the cost of health care, negotiated by their insurers, while 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. Under the ACA, nonprofit hospitals can no longer charge uninsured patients more than they generally bill insured patients for emergency and other medically necessary care. Unfortunately, this still leaves the uninsured unprotected because the policy does not apply to for-profit hospitals, which account for up to one fifth of all hospitals in the U.S. Additionally, it still leaves it up to the nonprofit hospital to determine who qualifies for charity care, which as discussed in Subsection 2, the hospital may not extend to everyone who qualifies.

Additionally, the ACA does not equalize the care provided to 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.” Yet, the article noted that one patient who could not afford the elite rooms was left in pain, on a gurney, without a bedpan.

Unequal treatment affects children as well. “[A] study of 965 children with acute asthma who were treated in emergency departments...
found that uninsured children consistently received lower quality of care than insured children.”

Institutional bias also prevents access to health care for these groups, because health care institutions are allowed to decide what hospitals to close and who qualifies for charity care.

2. Institutional Racial Bias

Examples of institutional racial 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 for economically disadvantaged minority children. Not all actions by an institution that disproportionately affect minorities and the economically 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. This still continues. 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. 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 and 2003, except between 1990 and 1997. Hence, research shows that as the percentage of African American residents increases in the neighborhood, hospital closures increase.

202. BAKER INST. POL’Y REP., supra note 170, at 3.


204. BEATRIX HOFFMAN, HEALTH CARE FOR SOME: RIGHTS AND RATIONING IN THE UNITED STATES SINCE 1930, at 151 (2012).


In fact, Dr. Sager has shown that forty-five percent of hospitals open in 1970 had closed by 2010, and of these hospitals sixty percent were in neighborhoods that were predominately African American.\textsuperscript{207} St. Louis and Detroit are poignant examples of these race-based hospital closures. St. Louis had eighteen hospitals in predominately African American neighborhoods. By 2010, all but one had closed.\textsuperscript{208} In 1960, Detroit had forty-two hospitals open in predominately African American neighborhoods; by 2010 only four were open.\textsuperscript{209}

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 thereby increasing health care costs.\textsuperscript{210} 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.\textsuperscript{211}

Not only is access to health care diminished because of a reduction of hospital services, but care also suffers because of physician departures.\textsuperscript{212} Once a hospital has closed or relocated, the physicians practicing in the area often follow the hospital to more affluent neighborhoods, thereby further disrupting the health care services in predominately African American neighborhoods.\textsuperscript{213} 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.\textsuperscript{214} This disruption in care is significant because many predominately African American neighborhoods already suffer from physician shortages prior to hospital closures and physician flight.\textsuperscript{215} As the number of primary care physicians decreases, African Americans


\textsuperscript{208}. \textit{Id.}

\textsuperscript{209}. \textit{Id.}

\textsuperscript{210}. \textit{See} Clark, \textit{supra} note 203, at 1035 (“Hospital closures set into motion a chain of events that threaten minority communities’ immediate and long term access to primary care, emergency and nonemergency hospital care . . . .”).

\textsuperscript{211}. \textit{Id.} at 1034–35.

\textsuperscript{212}. \textit{Id.} at 1034.

\textsuperscript{213}. \textit{Id.} at 1033.

\textsuperscript{214}. \textit{Id.}

are forced to seek care in emergency rooms and public hospitals, which are often understaffed and not adequately maintained.\(^216\) 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 nonprofit hospitals erect barriers to care for the economically disadvantaged by suing them for unpaid medical bills.\(^217\) These practices have continued even after the passage of the ACA, which tried to limit these aggressive collection practices.\(^218\) 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.\(^219\)

For example, in North Carolina, nonprofit hospitals have filed more than 40,000 collection lawsuits in a five-year period.\(^220\) Carolinas HealthCare system, a nonprofit health care system, 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.\(^221\) Many of the patients who were sued for unpaid bills were uninsured and were economically

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216. Clark, supra note 203, at 1035.


221. Id.
disadvantaged.222 Once the hospital wins the case and receives a judgment against the patient, it usually places a lien on the patient’s house.223 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 wage garnishments and 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 structural and institutional racial biases within the health care system, minorities and the economically disadvantaged lack access to medicine and 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 medical research to obtain access to health care. However, because of structural and institutional racial biases, once the medical research studies end, minorities and the economically disadvantaged do not receive the benefit of the studies because they cannot afford the medicine and lack access to health care.

D. The Effect of Bias on Medical Research

Researchers from health care institutions that deny minorities and the economically disadvantaged access to health care use these same populations as subjects for medical research studies. In fact, empirical data shows that in comparison with their percentage in the U.S. census, African American children continue to be overrepresented in non-therapeutic medical research studies and underrepresented in Phase III therapeutic medical research studies.224

This means that when compared to Caucasians, African American children participate in medical research studies that may or may not add to scientific knowledge that benefits the general society, but not in medical research studies that will be beneficial for them as a group. The literature suggests that the reason for this overrepresentation in non-therapeutic medical research studies is that African American children are overrepresented in economically disadvantaged neighborhoods, which house the academic medical centers that conduct medical research studies.225 Thus, African American children are included in medical research studies because of their proximity to the academic medical

222. Id.
223. Id.
225. Id. at 51–53. However, this still does not explain why African American children are not represented in Phase III therapeutic medical research studies conducted by academic medical centers in which treatment is a goal.
centers, not because the research addresses their populations’ health needs. Researchers who conduct medical research studies using economically disadvantaged minority children are often affiliated with health care institutions that prevent access to health care for economically disadvantaged minority children.

Although there is little research regarding how institutional decisions affect children’s access to health care, it is clear that institutional decisions limit access to health care for the economically disadvantaged and minority adults. This can have an indirect effect on children if the patients denied care are their parents. 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.226 Once the hospital wins the case and receives a judgment against the patient, it is allowed to garnish the patient’s wages—and if the state allows it, the hospital can also charge the patient interest on her bill.227

The hospital has also taken liens out on a patient’s home to recoup the costs of any judgments exceeding $1,000.228 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.229 Garnishments amount to one-half of one percent of the hospital’s revenues.230 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 for themselves and their children 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 medical research studies, which offer access to free health care only when the subject is participating in the medical research study.

In addition to the financial barriers to care, many hospitals refuse to treat certain uninsured and economically disadvantaged patients, often redirecting them to community hospitals or clinics, while using

227. Id. (describing how Heartland sued both adults in a household and garnished their wages, one at ten percent and the other at twenty-five percent, and also charged the patient nine percent interest on the bill).
228. Id.
229. Id.
230. Id.
them as research subjects in medical research. The University of Chicago Medical Center (Center) is a perfect example of this tension between denying care to minorities and the economically disadvantaged, while focusing on expanding medical research studies 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, elsewhere to community hospitals and clinics. Because the hospital is located in an economically disadvantaged area that is racially segregated, the people being redirected were disproportionately disadvantaged minorities. However, when the Center needed subjects for research, for studies, these people were solicited for participation in research because of their proximity to the hospital.

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. 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 as medical research subjects. 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. As discussed above, the Center still uses these people in medical research studies.

In the United States, structural and institutional racial biases prevent economically disadvantaged minorities from accessing health care.

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232. Ross, supra note 20, at 51–53.


235. Id. § 1395dd(b).


237. Id.
and medicine. These biases allow institutions to bring lawsuits for unpaid care and outright deny care because health care is delivered based on ability to pay, not need. Hence, even if economically disadvantaged minority children participate in a medical research study that finds a new treatment for a disease, the children will not have access to the treatment because structural and institutional racial biases prevent them from accessing the treatment once the study is completed. Thus, even if researchers have good intentions when they include economically disadvantaged minority children in medical research studies, it still may be exploitation, a violation of the Justice Principle, because the population from which the subject originates will not benefit from the research.

III. Ensuring Justice Is Fulfilled

Although arguments for inclusion were based on altruistic notions of providing everyone with a “fair opportunity” to participate in medical research studies to obtain access to treatment, it ignores structural and institutional racial biases that limit economically disadvantaged minority children’s access to health care and treatment after the medical research study ends, preventing them from benefiting from participation in medical research. In order to prevent exploitation of economically disadvantaged minority children, I suggest that the Justice Principle incorporate the Human Development Approach, which demands that researchers provide a benefit to the population from which the subjects originated that alleviates some of the population’s underlying problems, such as lack of access to health care. To ensure that there is a benefit that will alleviate some of the population’s underlying problems, I propose the use of the Vulnerability and Equity Impact Assessment (VEIA) tool, which I created based on the Health Equity Impact Assessment (HEIA) tool.238

Under the VEIA, the researcher must complete an introspective summary of their research that includes the purpose of the research, those affected by the condition being studied, whether the research is a priority to those affected with the condition, and pinpoint any disparities (age, racial, or class based) in the treatment of the condition. After completing this summary, researchers need to identify the structural and institutional racial biases that prevent economically disadvantaged minority children from accessing health care, the adverse impacts economically disadvantaged minority children will suffer as a result of their participation in the research, and whether participation in the medical research study will alleviate structural and institutional racial biases. If researchers determine that because of their status (age, social class, race) economically disadvantaged minority children are

238. Haber, supra note 18.
overburdened, then the researchers cannot use the children as research subjects.

Using the VEIA, a newly created Board of Children (Board for Children or the Board) would be responsible for approving all medical research studies seeking U.S. government funding that plan to use children. The completed tool should be posted on clinicaltrials.gov and used by the Board to determine if the researcher was fulfilling the benefit requirement of the Justice Principle. Redefining Justice to include the Human Development Approach, implementing the VEIA, and having the Board complete the VEIA before certifying research will begin to address the structural and institutional racial biases that lead to exploitation.

A. Ending Exploitation: Human Development Approach

Although originally couched in terms of global justice, the time has come to apply the Human Development Approach to medical research conducted in the United States on populations that suffer the same social and economic disadvantages as those in the developing world. This Approach offers insightful guidance on how to prevent the exploitation of economically disadvantaged minority children participating in medical research studies conducted in the United States.

1. Theory

The Human Development Approach is a means to combat the “minimalist view” that “accepts the status quo in the host community as the appropriate ‘normative baseline’ against which proposed research initiatives are evaluated—meaning that the status quo is treated as the threshold of a person’s moral entitlements in this particular sphere.” Because the minimalist is only worried about doing no harm (Nonmaleficence) and providing a benefit (Beneficence), then the status quo allows him to avoid questions of distributive justice. The status quo allows the minimalist to view harm as any additional damage greater than the status quo caused to the research subject and a benefit as any gain.

One example of the minimalist approach is the inclusion/fair opportunity theory that believes research is just if everyone is provided an opportunity to participate, regardless of whether the research will further burden the most disadvantaged of the population or provide them with a direct benefit. The inclusion/fair opportunity theory champions leaving up to the discretion of the researchers and the host country to conclude what will benefit research subjects. However, this theory leaves little room to determine what is a meaningful benefit for the

239. London, supra note 17, at 27.

240. See id. at 25 (“The debate about justice has become synonymous with the question of who gets access to the fruits of successful research.”).
research subject, because the power balance remains with the researcher and host country, not the research subject.241 Notwithstanding this power imbalance, proponents of this theory believe that the host country can bargain for a host of benefits that are comparable or better than benefits given in developed countries.242 However, in reality, the research subject is dependent on the charity of the researcher and the host country.

This minimalist approach also favors “justice as mutual advantage.”243 Proponents of the minimalist theory believe that researchers and research subjects receive a mutual advantage. Researchers obtain subjects and research participants receive bargained-for benefits. Yet, the Justice Principle is not about creating a mutual advantage; rather, it proscribes the duty researchers owe to their research subjects. As noted in the Belmont Report, the Justice Principle requires that researchers have a duty to assess whether potential research subjects and the population from which they come will benefit from the research.244 London notes that this duty flows from contractual and citizenship obligations.245

Specifically, in developing countries, researchers contract with government officials to use their citizens for medical research studies.246 However, the governments of some developing countries are often the cause of the poverty and poor health of their citizens. The failure to take this into consideration, and the broader social and economic context in which the research takes place, eliminates the information necessary to determine whether the researcher is contracting with those who have caused the social and economic disadvantages of the research population.247 “These failures can generate prior moral claims that the community members have against their own authorities, and such claims may constrain the range of cooperative or collaborative relationships in which researchers may permissibly engage.”248 By contracting with these governments, the researchers have become accomplices in

241. See id. at 26 (“[D]etails about the level and type of benefit require value judgments that are best left to the discretion of those in the host community.”).
242. Id.
243. Id. at 25 (citation omitted).
244. Belmont Report, supra note 5, at 23,194.
245. London, supra note 17, at 30 (“[D]uties of rectification may attach to researchers who work for or are funded by entities that have contributed more directly to the plight of developing world populations.”).
246. Id.
247. Id.
248. Id.
the devastation of these populations. To rid themselves of complicity, researchers have a special contractual duty to aid the populations they are using for research.249

Furthermore, as citizens of developed nations that have caused or facilitated the lack of access to health care and medicine in developing nations, the researchers have a duty to aid the populations they are using for research.250 London submits that “at the most general level duties of rectification may attach to all citizens of democratic nations whose policies and international activities have contributed to the plight of those in the developing world.”251 Policies that have contributed to the plight of those in the developing world, includes participation in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which protects pharmaceutical companies’ intellectual property rights across the world.252 Even though TRIPS allows for countries to import or produce generic versions of some medicines in cases of national emergency, United States pharmaceutical companies have aggressively pressed for trade sanctions or instituted legal action under TRIPS that have blocked legitimate efforts to provide medicines to developing countries in cases of national emergencies, such as the HIV/AIDS epidemic.253

This citizenship duty requires researchers to limit the use of individuals from developing countries to instances where the medical research studies will “expand the capacity of the host community’s basic social structures [] to meet the distinctive health priorities of that community’s members . . . .”254 Only then is it permissible to use a developing nation’s scarce public resources for medical research studies.255 Thus, medical research is acceptable if it functions “as a part of a division of labor in which the distinctive scientific and statistical methods of the research enterprise target and investigate the means of filling the gaps between the most important health needs in a community and the

249. Id.
250. Id.
251. Id. International activities that have contributed to the plight of individuals in developing nations also includes what Thomas Pogge calls “international resource privilege.” Id. This privilege is the ability to wrestle control away from legitimate developing country governments as a means to enrich the privileged few. Id.
252. Id. See also Cynthia Ho, Access to Medicine in the Global Economy: International Agreements on Patent and Related Rights (Oxford Univ. Press, 2011) (discussing TRIPS and its effects on access to medicine).
254. Id. at 33.
255. Id.
capacity of its social structures to meet them.” To be just in developing countries, research “must directly and indirectly expand the capacity of the host community’s basic social structures either to meet the distinctive health priorities of that community’s members or to meet their basic health needs under distinctive social or environmental circumstances.” If the country does not have an appropriate structure available, then the researcher must work with community and international groups to create a structure. The structure must be sustainable, and thus the research should serve as the anchor for which additional long-term aid can be provided.

Clearly, the injustices suffered by those in developing nations are not the full responsibility of the researchers. However, by using the citizens of these nations for their own benefits, researchers and their institutions have a duty to provide the research subjects with a meaningful benefit. The condition of providing sustainable social structures to improve health outcomes in the host community is not an onerous requirement.

This condition is easily fulfilled, for example, when developed countries collaborate on research that targets a common problem. When doing research in developing nations, it might be fulfilled if researchers can find host communities in which the target of a research program represents a health priority and where the resulting intervention could be implemented within the health structures of the host community.

Although couched in international terms, the Human Development Approach can also apply to the United States’s domestic problems of exploitation of economically disadvantaged children for the greater good.

2. Human Development in the U.S.

In the United States, researchers have the same contractual and citizenship obligations. In terms of contractual obligations, researchers in the United States have a duty to ensure that they are not contracting with those who have caused the social and economic disadvantages suffered by the potential research subjects. More specifically, researchers

256. Id.
257. Id.
258. Id. at 34.
259. Id. at 33.
260. Id.
261. Id. at 35.
should not contract with those who have caused structural and institutional racial biases to prevent economically disadvantaged minority children from accessing health care. For instance, researchers should not have contracted with states to enroll foster children in HIV/AIDS drug studies\textsuperscript{262} because, as discussed in Section II.C. and in more detail in subsection 1, states have failed to provide the children with adequate health insurance that would provide them with access to health care.\textsuperscript{263} Furthermore, the states failed to test the children to ensure that they suffered from HIV/AIDS, unnecessarily exposing the children to risk.\textsuperscript{264} The failures of the states to provide adequate health insurance and to test the children for HIV/AIDS creates prior moral claims that the children have against the states, which constrains the researchers’ ability to enter into a contract with the states. By contracting with the states, the researchers have become accomplices in the devastation of the children, which they can only rid themselves of by providing the children with a benefit that will alleviate some of their underlying problems. The researchers also have a citizenship duty.

The citizenship duty is based on researchers’ affiliation with institutions or hospitals that have erected insurmountable barriers to access to health care for economically disadvantaged minority children. As discussed in Section II.D., health care institutions have sued economically disadvantaged patients who qualify for charity care and denied care to economically disadvantaged and minorities.\textsuperscript{265} However, when seeking subjects for their medical research studies these same institutions seek out the same economically disadvantaged minority children they refused to treat. Denied access to health care, these economically disadvantaged minority children are willing to participate in medical research studies, even if access to health care is offered for a short duration of time.

By denying economically disadvantaged minority children access to health care, these institutions are creating a vicious cycle that will not be fixed until these institutions are required to provide a benefit to the population of economically disadvantaged minority children that will alleviate some of their underlying problems.

3. Applying the Approach to U.S. Research

Some may argue that the HIV/AIDS drug studies did not violate the Justice Principle because although the children suffered serious side effects including death, the children were going to die anyway from

\begin{itemize}
\item \textsuperscript{262} Solomon, \textit{supra} note 130.
\item \textsuperscript{263} See \textit{supra} note 189 (listing cases that involved challenges to the state for failure to access health care for child Medicaid recipients).
\item \textsuperscript{264} Yearby, \textit{supra} note 15, at 26, 32.
\item \textsuperscript{265} See \textit{supra} Part II.D.
\end{itemize}
HIV/AIDS, so there was no additional damage. Furthermore, the children gained a benefit because they were granted access to health care and investigational drugs during the study. This is the minimalist approach.266

The problem with researchers that use the minimalist approach is they only use morally relevant information regarding the social and economic context of the subjects267 in a manner that benefits their research. The reason that the research subjects are so attractive is because of their social and economic disadvantage. Thus, researchers capitalize on this advantage and use it as an entitlement to further exploit the vulnerable, using fair opportunity as a guise. However, when applying the Human Development Approach to the HIV/AIDS drug trials it is clear that the Justice Principle is not entitlement to research, rather it imposes specific requirements on researchers or their sponsoring agencies.268

Applying this Approach to the above-mentioned HIV drug study, it is clear that the researchers should never have contacted the States to enroll economically disadvantaged minority children in foster care to participate in the studies because at the time of the study it was not clear that the population was affected by the disease. More specifically, it was not clear that any of the children who participated in the studies even suffered from HIV/AIDS. Thus, researchers had a duty not to use foster children.

This duty arises from two relationships. First, the researchers were often contracting with states that had prevented economically disadvantaged children from accessing health care. Because researchers were contracting with States that had chosen to limit economically disadvantaged children’s access to medical care through under-funding of Medicaid, the researchers had a duty to alleviate some of the underlying problems faced by economically disadvantaged children, such as lack of access to medical treatment. Second, the researchers were citizens affiliated with institutions that denied access to care to economically disadvantaged minority children. If researchers decided to use economically disadvantaged minority children as subjects they had a duty to provide a benefit to the vulnerable population from which the subjects originate that alleviated some of the populations’ underlying problems, such lack of access to health care.

To measure whether the benefit will alleviate some of the populations’ underlying problems, I suggest that researchers be required to

266. London, supra note 17, at 26 (“[T]he minimalist view frames the fundamental problem of justice in international research in terms of two salient variables: the needs and vulnerabilities of the host population, and the capacity of research to benefit and to burden.”).

267. Id. at 28.

268. Id. at 34–35.
use the VEIA tool. The VEIA is based in part on Health Equity Impact Assessment tools.

B. Measuring Justice: Vulnerability and Equity Impact Assessment Tool

In 1970, the United States became the first country to require impact assessments to attempt to predict the impact of policies on environmental health. Since 1999, many countries, such as Germany, Switzerland, the Netherlands, Australia, New Zealand, Canada, and the United States, have adopted this tool for use in the health policy field to avoid or minimize negative impacts on health. Impact assessment tools put the burden on those completing the tool to show that their actions will not negatively impact the health of the population.

The Health Impact Assessment (HIA) is “a combination of procedures, methods and tools by which a policy, programme or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population.” There are two main functions of the HIA: 1) to support policy making when choosing between options; and 2) to predict the future consequences of implementing different policy options. There are six key stages in using a HIA: “screening, scoping, data collection, impact appraisal, reporting/recommendations, and monitoring/evaluation.” By using the HIA, policymakers can adopt the most beneficial policy for the population’s health. Attaining equity in health can be one of the priorities in completing a HIA. However, equity is not the main focus of the HIA. Although the HIA can determine if the policy will have different 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 Health Equity Impact Assessment (HEIA) tool was created to ensure that assessments about a policy’s impact would

269. HABER, supra note 18.
272. Id. at 3. (citation omitted).
273. Id.
275. Id. at 629.
276. Id. at 622. This study found that even when equity was a central theme of the HIA, the impact analysis did not go beyond identifying vulnerable populations and the differential effects of the policy on these populations. Id. at 629.
include an evaluation of fairness and equity as well as root causes of inequities.\textsuperscript{277} The HEIA identifies “deeply rooted disparities in income, wealth, knowledge, social status and connections” as “[f]undamental causes” of health inequity.\textsuperscript{278} The World Health Organization’s Commission on Social Determinants of Health has recommended the use of the HEIA in all global, national, and local policy making.\textsuperscript{279} New Zealand, Australia, Canada, the United Kingdom, the United States, and other countries currently use the HEIA.\textsuperscript{280} There are five steps involved in completing a HEIA:

1. Screening
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 \textbf{all} initiatives be screened.

2. Scoping
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
Use available data/evidence to prospectively assess the impacts 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.
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
Develop evidence-based recommendations to minimize or eliminate negative impacts and maximize positive impacts on vulnerable or disadvantaged groups. These recommendations comprise

\begin{itemize}
\item\textsuperscript{277} Id. at 629.
\item\textsuperscript{278} Id. at 631–32.
\item\textsuperscript{279} Id. at 631.
\item\textsuperscript{280} ONTARIO MINISTRY OF HEALTH AND LONG-TERM CARE, HEALTH EQUITY IMPACT ASSESSMENT (HEIA) WORKBOOK 8 n.1 (2012) [hereinafter HEIA Workbook].
\end{itemize}
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
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.281

Once these steps have been completed, the organization must decide whether or not to implement the policy.

A Racial Equity Impact Assessment (REIA) tool has also been created to identify the impacts of policies on racial and ethnic groups.282 Governments in Iowa, Connecticut, Seattle, and the United Kingdom have adopted the REIA.283 Although the primary focus of the HEIA and REIA are to reduce health inequities, I believe that with some modification these tools can be used to create a VEIA to determine whether economically disadvantaged minority children should participate in medical research studies.

Specifically, the VEIA should be used to assess whether a proposed medical research study will provide a benefit to economically disadvantaged minority children that will alleviate some of the underlying problems that prevent them from accessing health care. While in this Article, I focus on how the VEIA can be used to protect economically disadvantaged minority children, I believe that the VEIA can be used to protect all vulnerable populations.284

281. Id. at 14–15. The HEIA Workbook lists “Dissemination” as a fifth step, which “involves sharing results and recommendations for addressing equity. Dissemination is a cyclical process, interacting with step four (monitoring).” Id. at 15. Here, the screening process, where it is decided whether the HEIA applies, is treated as step one.


283. Id.

284. The VEIA can also be used to measure whether researchers are complying with informed consent. Ruqaijah A. Yearby, Involuntary Consent: Conditioning Access to Health Care on Participation in Clinical Trials, 44 J.L. Med. & Ethics 445–61 (2016); Yearby, supra note 15.
1. The VEIA

First, the researcher must screen the research proposal to identify the purpose of the research, what the research seeks to accomplish, and whether the research will impact the health and well-being of economically disadvantaged minority children. Additionally, the researcher must discuss whether the research is a priority for economically disadvantaged minority children. This review coincides with the current requirement of showing that the research will add to generalizable scientific knowledge.285

In order, to answer this question, the researcher must engage economically disadvantaged minority children or someone who represents their interests, such as child advocates from non-governmental agencies like Marian Wright Edelman, the President and Founder of the Children’s Defense Fund.286 This screening dovetails with procedures used by researchers when they conduct international research to ensure that the research is culturally competent.287 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. If economically disadvantaged minority children are most affected by the condition, are there other less vulnerable populations that can be used for the research?
3. Will the research alleviate some of the populations’ underlying problems?
4. Will the population from which the subjects originate gain access to the treatment after the study is concluded?

If economically disadvantaged minority children are most affected by the condition, then the researcher must assess whether the impacts on this population will be negative or positive. To complete the impact assessment step, a researcher 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

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285. The OHRP Guidebook concerning medical research adds minorities to the list of vulnerable populations. OHRP, INSTITUTIONAL REVIEW BOARD GUIDEBOOK (1993) (on file with the author).


287. Id.
consultation with experts or members of the affected groups.”288 The evidence should be used to answer the following questions:

1. Disparities:
   a. Are there race, class, and/or age disparities in the number of people who suffer the condition or survive from the condition?
   b. Which racial/ethnic groups are currently most advantaged and most disadvantaged by the issues this research seeks to address?
   c. Which socioeconomic groups are currently most advantaged and most disadvantaged by the issues this research seeks to address?
   d. Which age groups are currently most advantaged and most disadvantaged by the issues this research seeks to address?
   e. How are the advantaged and disadvantaged groups affected differently?
   f. What quantitative and qualitative evidence of inequality exists?
   g. What evidence is missing or needed?
   h. Will the research exacerbate these disparities?289

2. Burdens:
   a. What are the barriers to accessing health care for economically disadvantaged minority children who are potential research subjects?
   b. Will participation in medical research studies increase these barriers?
   c. Will participation in medical research studies alleviate these barriers?
   d. What are the root causes of the barriers to accessing health care, such as structural and institutional racial biases?
   e. Will the research address these root causes?

3. Adverse Impacts:
   a. What potential adverse impacts or unintended consequences could result from participation in this research beyond the burdens?
   b. Will the impacts or unintended consequences further burden economically disadvantaged minority children?
   c. How could adverse impacts be prevented or minimized?

4. Equitable Impacts:
   a. What are positive impacts on the populations underlying problems, such as increased access to health?

289. See Keleher, supra note 282, at 30 (providing sample questions to assist in assessing the impact of proposed actions on various racial groups).
b. Which racial/ethnic groups could benefit?
c. Which socioeconomic groups could benefit?
d. Which age groups could benefit?
e. Are there further ways to alleviate some of the populations’ underlying problems?290

Using the answers from these questions, the researcher must provide an evidence-based determination of whether economically disadvantaged minority children should be used as research subjects because the research will alleviate some of the populations’ underlying problems, such as access to health care.

If the researcher decides to use economically disadvantaged minority children as research subjects even though there is a possibility of increasing barriers to health care, the researcher must develop a mitigation strategy that will alleviate another underlying problem of economically disadvantaged minority children such as access to essential goods such as food, education, and housing. If there is a mitigation strategy, the researcher must monitor the actual strategy and show that the strategy has alleviated another underlying problem.

2. Applying the VEIA

If researchers are required to apply the VEIA, many research studies that exploited economically minority children in violation of the Justice Principle would never have been funded.

For example, if the researchers discussed in Section II.B., who used African American and Latino foster children to test HIV/AIDS drugs, had been required to complete a VEIA, it would have shown the research violated the Justice Principle.

First, the researchers would have been required to screen the research to identify the purpose of the research, what the research sought to accomplish, and whether the research had the potential to affect economically disadvantaged minority children.291

Clearly, the screening would have shown that the medical research study had the potential to impact economically disadvantaged minority children if they were used as subjects, and it was unclear why healthy children had to be used to test HIV/AIDS drugs. Furthermore, there was no evidence that this research was a priority to healthy economically disadvantaged minority 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. There was no evidence that at the time of the research economically African American and Latino children were the group most affected by HIV/AIDS. Therefore, other children should have been used. Moreover, the impact assessment of the disparities, the burdens, the adverse impacts, and the equitable impacts

290. Id.

291. See supra Section III.B.1.
would have shown that economically disadvantaged minority children were negatively impacted with little to no benefit. Specifically, economically disadvantaged minority children were not the group most affected by HIV/AIDS (disparities) and the children had barriers to accessing health care because they used Medicaid (burdens). The research did not address these barriers. In fact, the research increased these barriers by making healthy children sick, who had limited access to health care (adverse impacts) and did not provide any positive impacts in terms of treatment or increasing access to health care (equitable impacts). Thus, the children should not have participated in the medical research studies.

This is just one example of how using the VEIA to measure the redefined Justice Principle will protect economically disadvantaged minority children from being exploited. However, the incorporation of the Human Development Approach in the Justice Principle and implementation of the VEIA will not put an end to exploitation without changing the current regulatory structure governing medical research studies involving children.

C. A New Regulatory Structure

In the past OHRP and individual IRBs have been responsible for preventing economically disadvantaged minority children from being exploited in medical research studies. The examples discussed in Section II.B. suggest that neither OHRP nor individual IRBs have been successful in accomplishing this task. Thus, I suggest the creation of a U.S. Human Research Protection Review Board for Children using the authority granted by the Common Rule to review medical research studies otherwise unapprovable.

The Board for Children would be in charge of determining whether domestic medical research studies involving children were ethical based upon the redefined Justice Principle. Before a medical research study is conducted, the Board of Children would be required to review the research proposal, including the VEIA, to evaluate whether the research exploits economically disadvantaged minority children for medical research studies in violation of the redefined Justice Principle.

To accomplish this task for research governed by the Common Rule, the Board for Children needs to have adequate community participation and specific requirements for the approval of research. The Board for Children must include at least two members of each group identified as a vulnerable population in the Common Rule. The Board for Children must also consist of at least two physicians that conduct

292. 45 C.F.R. § 46.103(b)(1) (2015); OHRP Memorandum, supra note 81.
294. In addition, the Board can review issues regarding Autonomy and Beneficence.
research. However, these physicians cannot be from institutions that
deny children access to health care or have been cited for violations by
the OHRP. Finally, the Board for Children should include three bio-
ethicists, two child advocacy members, and two government employees.

The Board must review the VEIA for all medical research studies
using children governed by the Common Rule to ensure the studies
comply with the redefined Justice Principle. This review must occur
before the researcher submits the proposal for funding. The Board
would be responsible for reviewing the VEIA for each research proposal
to make sure that the study was not exploiting economically disadvan-
taged minority children for medical research studies. If the VEIA
shows that there is no exploitation and that the study was necessary
and safe, then the Board should approve the study and post the VEIA
on clinicaltrials.gov.

The creation of the Board is just the beginning of the structural
changes that need to be made to the regulation of medical research
studies using children. Additionally, new penalties need to be imposed
if a researcher and/or institution violates the Justice Principle. Curr-
ently, OHRP just issues letters and suspends researchers from federally
funded research. Violations of the Justice Principle should also result
in fines, loss of federal funding, and denial of drug approval. Researchers
that violate the requirements should also face criminal fines. Furthermore, victims of research conducted in violation of the Justice Prin-
ciples should be granted a private right of action against the institution
and the researcher.

CONCLUSION

Professor Patricia King, one of the drafters of the Belmont Report,
noted, “[d]espite common recognition that ‘the Tuskegee Study is Am-
rica’s metaphor for racism in medical research,’ there has been inade-
quate attention paid to race, either in the sense of negative and diff-
erential treatment or in terms of pervasive scientific racism, in the con-
struction of bioethics in the United States.” Specifically, neither re-
searchers nor those who regulate medical research studies take into acc-
ount structural and institutional racial biases that prevent vulnerable

295. The Board would also be responsible for ensuring that the researchers are
complying with the other requirement of Justice, which is that members of
the vulnerable population participating in the study will directly benefit from
the study.

296. See, e.g., Richardson, supra note 86, at 127 (discussing the potential deter-
rent effect of criminal punishment on researchers).

297. Patricia A. King, Reflections on Race and Bioethics in the United States, 14
to Tuskegee’s Truths, supra note 14, at 3).
populations, such as economically disadvantaged minority children, from accessing health care, making them vulnerable to exploitation in medical research studies that promise access to health care. Thus, economically disadvantaged minority children continue to be exploited in medical research studies that do not provide a benefit to the population from which they originated.

As Carol Levine notes, “[t]here [has been] no resolution of the conflict between American society’s failure to provide basic healthcare 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.” 298 Hence, the time has come to put an end to this exploitation by enforcing the Justice Principle to prevent the use of all children, but especially economically disadvantaged minority children, in medical research studies for which they will not receive a benefit. This will only happen if the Justice Principle stands for more than inclusion. The Justice Principle must be a measurable standard that ensures fairness, equity, and the right of children to reach their full health potential without interference. Otherwise, children will continue to be sacrificed for the benefit of an unworthy society.

298. Levine, supra note 1, at 121.