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Introduction

An estimated 20–30% of all United States clinical trials are outsourced to countries such as Poland, India, and Mexico.[1] For both domestic and outsourced clinical trials, language barriers and a lack of cultural understanding are a constant source of problems.[2] In 1993, the National Institutes of Health Revitalization Act (NIHRA) was passed with a provision requiring minorities and women to be included in clinical research.[3] Section 131 of the Act was passed in an attempt to prevent and correct the frequent exclusion and improper treatment of minority participants in clinical research.[4] The Act applies to research being conducted or supported by the National Institute of Health,[5] and provides that minorities should be included as subjects, unless an exception applies rendering the requirement inapplicable.[6] In practice, researchers still have difficulty including diverse

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1. Karen Politis Virk, *Global Clinical Trials: The Challenge of Language*, LANGUAGE CONNECTIONS, http://www.languageconnections.com/descargas/Global%20Clinical%20trials%20challenge%20of%20language.pdf (last visited Sept. 22, 2011) (citing Press Release, Thomson CenterWatch, Thomson CenterWatch Tracks Emerging Markets of Clinical Research (Apr. 19, 2007) (on file with author)).

2. *Compare* Virk, *supra* note 1 (discussing the challenges of international clinical research), *with* Ctr. for Translational Sci. Activities, *Community Engagement and Minority Inclusion*, MAYO CLINIC, http://ctsa.mayo.edu/resources/community-engagement-minority-inclusion.html (last visited Sept. 22, 2011) (providing guidance for clinical researchers within the United States).

3. National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 289a-2 (2006).

4. NAT'L INSTS. OF HEALTH OFFICE OF THE DIR., U.S. DEP'T OF HEALTH & HUMAN SERVS., OUTREACH NOTEBOOK FOR THE INCLUSION, RECRUITMENT AND RETENTION OF WOMEN AND MINORITY SUBJECTS IN CLINICAL RESEARCH 3–4 (2002) [hereinafter OUTREACH NOTEBOOK].

5. *Id.*

6. 42 U.S.C. § 289a-2(b).

populations in clinical research.[7] This is especially true with nonfluent English speakers because of the practical difficulties of providing translations and interpretations, ensuring informed consent, and complying with necessary follow-up.[8] Furthermore, as occasionally happens with legislation, the vagueness of the Act's language allows researchers to avoid including certain minorities.[9] For example, the Act does not specifically address nonfluent English speakers or those with unique cultural attributes,[10] allowing these segments of the population to be excluded.[11] Great strides have been made since minorities first became part of clinical research,[12] but there is still a need for more comprehensive legislation.[13]

This Note examines the inclusion of diverse populations in clinical research, specifically addressing the difficulty of considering participants' cultural differences.[14] Part I of the Note

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7. THE ENDOCRINE SOC'Y, INCREASING MINORITY PARTICIPATION IN CLINICAL RESEARCH 1 (2007).

8. E-mail from Sara DeSanto, Assoc. Gen. Counsel, Allina Hosps. & Clinics, to author (Sept. 13, 2010, 12:46 CST) (on file with author); *see also* Yael Schenker et al., *The Impact of Language Barriers on Documentation of Informed Consent at a Hospital with On-Site Interpreter Services*, 22 J. GEN. INTERNAL MED. 294, 294 (2007) (discussing the impact of language barriers on the process of informed consent in hospitals).

9. *See* 42 U.S.C. § 289a-2 (providing that women and "members of minority groups" should be included unless certain exceptions apply, including if researchers feel inclusion "is inappropriate").

10. *Id.*

> Various subtle cultural differences can affect the way that clinical research is conducted. For example, many cultures do not believe in fully disclosing a patient's diagnosis; therefore, the potential risks of a clinical study may also be culturally filtered. This can negatively affect the process of informed consent. Another cultural difference which can interfere with patient informed consent involves the patient/physician relationship. More specifically, in many cultures patients are less likely to question a physician's recommendations.

Virk, *supra* note 1.

11. *See* 42 U.S.C. § 289a-2; Ctr. for Translational Sci. Activities, *supra* note 2 (offering advisors to help with inclusion of different cultural aspects in clinical research).

12. *See, e.g.*, FRED D. GRAY, THE TUSKEGEE SYPHILIS STUDY: THE REAL STORY AND BEYOND 48–73 (1998) (providing an example of minority involvement in an early clinical study).

13. Paula Hartman Cohen, *Comparative Effectiveness Research: Boon or Burden for Minorities?*, JUSTGARCIAHILL 1, 4–6 (2009), http://justgarciahill.org/ (search "Paula Hartman Cohen").

14. *See* Ctr. for Translational Sci. Activities, *supra* note 2 ("[L]anguage, health beliefs, religion and more can hinder participation in clinical research. Knowledge of cultural backgrounds and issues of concern to different communities are essential in understanding the needs of the groups before research can begin."). Many researchers mistakenly consider translating research documents into the participant's language to be enough. *See* Virk, *supra* note 1.

explores the history of clinical research and the exclusion and manipulation of minorities in clinical research. Part II discusses the background and requirement of informed consent. Part III discusses laws and efforts to include minorities in clinical research. The final section focuses on the difficulties and inequalities faced by non-English speakers participating in clinical research. The Note concludes with recommendations for amending the laws to ensure that all populations have appropriate access to clinical trials.

I. Background of Minorities in Clinical Research

A. *Clinical Research*

Clinical research has a variety of definitions, both broad and narrow.[15] These definitions impact the amount of research that is considered to be clinical research as well as what rules should be followed.[16] Clinical research is used for multiple purposes, such as testing new treatments for diseases and ailments, testing a body's interaction with new medications, and learning more about diseases.[17] It is a tool that was used by the ancient Egyptians[18] and Chinese[19] and has evolved over time.[20]

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15. *Compare* John I. Gallin, *A Historical Perspective on Clinical Research*, *in* PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH 1, 1 (John I. Gallin & Frederick P. Ognibene eds., 2d ed. 2007) (defining clinical research broadly using the definition of the Association of American Medical Colleges Task Force on Clinical Research: "a component of medical and health research intended to produce knowledge essential for understanding human disease, preventing and treating illness, and promoting health"), *with What Is Clinical Research?*, NAT'L INSTS. HEALTH: EUNICE KENNEDY SHRIVER NAT'L INST. CHILD HEALTH & HUMAN DEV., http://www.nichd.nih.gov/health/clinicalresearch/ (last updated July 23, 2009) (offering a more narrow definition of clinical research: "research that either directly involves a particular person or group of people or uses materials from humans, such as their behavior or samples of their tissue, that can be linked to a particular living person").

16. *See What Is Clinical Research?*, *supra* note 15.

17. *See* Gallin, *supra* note 15 (explaining that studies involve "interaction with patients, diagnostic clinical materials or data, or populations, . . . disease mechanisms; translational research; clinical knowledge; detection; diagnosis and natural history of disease; therapeutic interventions including clinical trials; prevention and health promotion; behavioral research; health services research; epidemiology; and community-based and managed care-based research").

18. *Id.* Imhotep, an Egyptian living around 3000 BC "was a known scribe, priest, architect, astronomer, and magician (medicine and magic were used together), and he performed surgery, practiced some dentistry, extracted medicine from plants, and knew the position and function of the vital organs." *Id.* (citations omitted).

19. *Id.* "[I]n 2327 BC Shen Nung, the putative father of Chinese medicine, experimented with poisons and classified medical plants, and I. Yin . . . , a famous

Depending on what type of trial is underway, the process for clinical research varies.[21] Generally, the process involves trying new therapies or medications, "evaluating the outcomes, and publishing the results."[22] Before clinical research can begin, it must receive approval from the Food and Drug Administration.[23] Once approved, the four phases[24] of clinical trial research begin.[25]

In addition to contributing to medical knowledge, clinical research creates an opportunity for "free or reduced-cost access to experimental therapies . . . for which insurance reimbursement [would be] unlikely."[26] Furthermore, it can be an alternative means for those without health insurance to gain access to the health care system.[27] Others have even concluded that there is an "inclusion benefit" achieved through participation in clinical trials.[28] Medicare beneficiaries currently receive coverage for the cost of routine patient care during clinical research participation,[29] but some have expressed concern about the American Recovery

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prime minister of the Shang dynasty, described the extraction of medicines from boiling plants." *Id.* (citations omitted).

20. *Id.* at 1–12.

21. Nat'l Insts. of Health, *Understanding Clinical Trials*, CLINICALTRIALS.GOV, http://clinicaltrials.gov/ct2/info/understand#Q04 (last updated Sept. 20, 2007) [hereinafter *Understanding Clinical Trials*].

22. John D. Lantos, *The "Inclusion Benefit" in Clinical Trials*, 134 J. PEDIATRICS 130, 130 (1999).

23. Ron Chea, *Clinical Research Trials Process*, SUITE101 (Mar. 28, 2010), http://www.suite101.com/content/clinical-research-trials-process-a219144. Note that "[u]sually, after 30 days, when the sponsors have not heard anything from the FDA, they can start the study without checking with the FDA." *Id.*

24. *Id.* Phase I of drug trials involves "determin[ing] the acceptable drug dosage, its route of administration, and its side effects. They also look at how the investigational drug is metabolized in humans' body [sic] and how the body acts on the new drug." *Id.* During Phase II, the research is centered on collecting evidence that supports the claims of the new medication's efficacy. *Id.* Phase III involves comparing the "new drug with the current drug that exists in the market. If the investigational drug is more efficacious than the current drug, the sponsors file a New Drug Application (NDA) with the FDA so that the sponsors could market the new drug to the public." *Id.* Finally, in Phase IV, researchers complete a "post-market study" with people who have been using the drug while it has been on the market and consider other possible uses. *Id.*

25. *Id.*; *see also* NESBITT, CLINICAL RESEARCH: WHAT IT IS AND HOW IT WORKS 4–8 (Chambers Moore ed., 2004).

26. Barbara A. Noah, *The Participation of Underrepresented Minorities in Clinical Research*, 29 AM. J.L. & MED. 221, 226 (2003).

27. *See id.* at 221–22.

28. Lantos, *supra* note 22. One example of an inclusion benefit occurred when infants who were enrolled in a clinical trial, but received the placebo, had better outcomes than infants who were not enrolled. *Id.*

29. Noah, *supra* note 26, at 227.

and Reinvestment Act[30] and the impact comparative effectiveness research would have on the minority population.[31]

Participants in clinical trials face an inherently uncertain element of risk.[32] They may experience "physical (death, disability, infection), psychological (depression, anxiety), economic (job loss), or social (for example, discrimination or stigma from participating in a certain trial)" risks, all of which may range in severity.[33] Although adverse events are documented for future use,[34] the results can be long-term for the participant.[35] Ultimately, clinical researchers should always attempt to minimize risks for participants.[36]

B. Minorities Manipulated in or Excluded from Clinical Research

Minorities have traditionally been excluded from clinical research.[37] "For reasons of scientific and practical convenience, minority groups were commonly excluded from clinical trials until the mid-1990s."[38] If not excluded, only a small percentage of the minority population was included in a particular study.[39] On numerous occasions, minorities were manipulated in clinical trials

30. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.

31. Cohen, *supra* note 13. Congressional Black Caucus members feared that research would be used to develop "a 'one-size-fits-all' approach to treating patients, . . . negatively [impacting] anyone outside the majority." *Id.* They were further concerned that the research would be used as a tool to "ration care," while not considering "the impact of race, ethnicity, gender and geography on health and health care." *Id.*

32. Nat'l Insts. of Health, *Ethics in Clinical Research*, NIH & CLINICAL RES., http://clinicalresearch.nih.gov/ethics_guides.html (last visited Sept. 22, 2011).

33. *Id.*

34. Lantos, *supra* note 22. The Systematic Evaluation of Research Risks (SERR) is used as a mechanism to evaluate risks. Annette Rid et al., *Evaluating the Risks of Clinical Research*, 304 JAMA 1472, 1472 (2010) ("[The SERR system] evaluates the risks of research interventions by comparing these interventions with the risks of comparator activities that have been deemed acceptable.").

35. Nat'l Insts. of Health, *supra* note 32.

36. *Id.*

37. Noah, *supra* note 26, at 225 ("[A] trend of under-inclusion of minorities in research for reasons of scientific convenience . . . contribute[s] to lower participation rates . . . ."). "Clinical trials for heart failure therapies also tend to exclude non-white patients." *Id.* at 226. "Of thirteen studies that examined the efficacy and/or safety of antihypertensive drugs . . . only eight of them enrolled at least one African-American subject, and investigators attempted to identify race-based differential drug response in only one study." *Id.*

38. Noah, *supra* note 26, at 224.

39. Craig K. Svensson, *Representation of American Blacks in Clinical Trials of New Drugs*, 261 JAMA 263, 264 (1989).

by being given false or misleading information.[40] Another study found that "[e]ight studies [out of seventy-two] explicitly stated they were on Caucasians or whites, and two excluded ethnic minority groups using language and birthplace criteria."[41] Learning from past injustices can help avoid similar treatment of other underrepresented segments of the population.

1. Past Injustices

There is a long history of minorities being manipulated and misled in clinical research; some instances are more well-known than others.[42] Many of the lesser-known early studies in the United States involved slaves.[43] "During the nineteenth century, 'researchers' used African-American slaves as unwilling subjects in a host of experiments dealing with medical phenomena such as sunstroke, the perfection of surgical techniques and dissection after death to improve their understanding of anatomy."[44] Government agencies, such as the United States Publich Health Service, supported studies that involved the manipulation of minorities.[45]

The Tuskegee study is one of the best-known examples of abuse in clinical research.[46] The study was held at the Tuskegee Institute in Macon County, Alabama, an area known as the "'Black Belt' because of its rich soil and vast number of black sharecroppers who were the economic backbone of the region."[47] The Tuskegee study, which ended forty years ago, ran from 1932

40. *See U.S. Public Health Service Syphilis Study at Tuskegee*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tuskegee/index.html (last visited Sept. 19, 2011).

41. Meghna Ranganathan & Raj Bhopal, *Exclusion and Inclusion of Nonwhite Ethnic Minority Groups in 72 North American and European Cardiovascular Cohort Studies*, 3 PLOS MED. 329, 331 (2006).

42. *See, e.g.*, *U.S. Public Health Service Syphilis Study at Tuskegee*, *supra* note 40.

43. Marcia Killien et al., *Involving Minority and Underrepresented Women in Clinical Trials: The National Centers of Excellence in Women's Health*, 9 J. WOMEN'S HEALTH & GENDER-BASED MED. 1061, 1063 (2000). "In the 1800s, for example, Dr. J. Marion Sims, the father of modern gynecology, specifically purchased [B]lack African slaves to perfect gynecological surgical procedures before he would try them on white women." *Id.*

44. Noah, *supra* note 26, at 229.

45. *See U.S. Public Health Service Syphilis Study at Tuskegee*, *supra* note 40.

46. *See, e.g.*, *The Tuskegee Study (1930s–1872)*, INSIDE NAT'L ARCHIVES S.E. REGION, http://www.archives.gov/southeast/exhibit/6.php (last visited Sept. 22, 2011); *U.S. Public Health Service Syphilis Study at Tuskegee*, *supra* note 40.

47. *About the USPHS Syphilis Study*, TUSKEGEE U., http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center/about_the_usphs_syphilis_study.aspx (last visited Sept. 22, 2011).

through 1972.[48] Formally called "Tuskegee Study of Untreated Syphilis in the Negro Male," the purpose of the study was to observe the "natural history of Syphilis in Blacks."[49] The study included a total of 600 men: "400 [already] syphilitic men, . . . [and] 200 uninfected men who served as controls."[50] Researchers offered multiple incentives to the participants.[51] However, the participants were misled about the purpose of the study.[52]

From 1936 through the 1960s, reports on the study were published every four to six years.[53] An Associated Press reporter unveiled the study to the media in 1972; when the public learned of this study they were outraged.[54] The study only ended after the story went to press.[55] By that time, only 74 of the 600 study participants were still living, and it is estimated that as many as 100 participants died from their untreated syphilis.[56] In 1974, an out-of-court settlement was reached in which the United States "government promised to give lifetime medical benefits and burial services to all living participants."[57] "The Tuskegee Health Benefit Program (THBP) was established to provide these services."[58] Wives, widows, and offspring of study participants were added as beneficiaries the following year.[59] Twenty-two years later, President Clinton issued a public apology.[60]

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48. *See U.S. Public Health Service Syphilis Study at Tuskegee*, *supra* note 40.

49. *About the USPHS Syphilis Study*, *supra* note 47.

50. Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, *in* ETHICAL ISSUES IN MODERN MEDICINE: CONTEMPORARY READINGS IN BIOETHICS 727, 727 (Jon-David Hague ed., 6th ed. 2003).

51. *About the USPHS Syphilis Study*, *supra* note 47. The participants were offered "medical exams, rides to and from the clinics, meals on examination days, free treatment for minor ailments and guarantees that provisions would be made after their deaths in terms of burial stipends paid to their survivors." *Id.*

52. *See id.* "Researchers told the men participating in the study that they were to be treated for 'bad blood.' This term was used locally by people to describe a host of diagnosable ailments including but not limited to anemia, fatigue, and syphilis." *Id.*

53. Brandt, *supra* note 50.

54. *About the USPHS Syphilis Study*, *supra* note 47.

55. Brandt, *supra* note 50, at 728.

56. *Id.*

57. *U.S. Public Health Service Syphilis Study at Tuskegee, The Tuskegee Timeline*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tuskegee/timeline.htm (last updated June 15, 2011).

58. *Id.*

59. *Id.*

60. *U.S. Public Health Service Syphilis Study at Tuskegee, Presidential Apology*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tuskegee/clintonp.htm (last updated Jun. 15, 2011).

Unethical research has also been carried out on minorities in a variety of other settings.[61] In the 1950s, Sloan-Kettering Institute researchers and Ohio State University medical researchers injected live cancer cells into prisoners at an Ohio state prison in a National Institutes of Health-sponsored study—half of the prisoners were Black.[62] During the same decade, the Army and the United States Atomic Energy Commission sponsored research performed on burn victims at the Medical College of Virginia.[63] The burn victims never provided their consent.[64] The majority of those included in the study were Black as well.[65] The participants were injected with radioactive isotopes; in some cases, the amount was fifty times the "maximum permissible level" for a "normal human being."[66] Holmesburg Prison in Pennsylvania allowed a study to be conducted in which prisoners, who were mostly Black, were injected with dioxin, an incredibly toxic by-product of an herbicide.[67] Similar to the Tuskegee Study, many participants stated they had taken part in the research because it offered incentives, such as money.[68] Often, researchers either did not tell inmates the entirety of what they would be exposed to.[69] In other situations, the language was so

61. *See* ALLEN M. HORNBLUM, ACRES OF SKIN 16–17 (1998) (describing the dangerous scientific experiments conducted on Black prisoners at Holmesburg Prison in the 1950s).

62. *See id.* at 93; Mike Adams, *Vaccines and Medical Experiments on Children, Minorities, Woman and Inmates (1845–2007)*, INFINITE UNKNOWN (Apr. 18, 2010), http://www.infiniteunknown.net/2008/04/18/vaccines-and-medical-experiments-on-children-minorities-woman-and-inmates-1845-2007-2/.

63. *See Public Meeting Before the Advisory Comm. on Human Radiation Experiments* (1995) (statement of Cliff Honicker), *available at* http://www.gwu.edu/~nsarchiv/radiation/dir/mstreet/commeet/meet11/trnsc11a.txt [hereinafter *Public Meeting*].

64. *Id.*

65. *See* HARRIET A. WASHINGTON, MEDICAL APARTHEID 237 (2006).

66. *See Public Meeting*, *supra* note 63 (explaining that some study participants were injected with 500 micro-curies of Phosphorus-32).

67. HORNBLUM, *supra* note 61, at 163–64, 171–73 (stating that dioxin, commonly known as Agent Orange, is linked to "cancer, birth defects and fetal cancer").

68. *Id.* at 21–23. It seems inmates wanted money for a variety of reasons. One former inmate said inmates wanted the money "so they didn't have to wheel and deal for things." *Id.* at 23. He also said that the money earned from volunteering in the experiments "would have been 'really helpful' to him when he left the prison, if he hadn't squandered it when he was released." *Id.* Money raised from the experiments could also help some inmates raise the money needed for bail; they "could raise the 10 percent bail bond required for freedom." *Id.* Further, the money could be used to "hire an attorney . . . before a forthcoming trial[, which] was a constant preoccupation among these inmates." *Id.* at 24. Finally, the money could be used at the prison commissary to buy treats and personal items. *Id.*

69. *Id.* at 26–27. Vague language mystified what was actually occurring in the

technical that the inmates could not understand it.[70] One doctor who conducted research at the prison, Dr. Klingman, expressed his excitement for the potential research opportunities at Holmesburg Prison: "'All I saw before me were acres of skin. It was like a farmer seeing a fertile field for the first time.' The . . . inmates . . . represented a unique opportunity for unlimited and undisturbed medical research."[71]

American companies have a history of conducting unethical research abroad and in United States territories. In a recent example, Nigerian children and their guardians sued Pfizer, alleging that the company tested experimental antibiotics on the children without their consent.[72] That case is reminiscent of the clinical trials that occurred in Puerto Rico during the development of the birth control pill.[73] In the oral contraceptive trials that occurred in Boston, "another group [of trial participants] were given [an] experimental drug without their direct consent."[74] The oral contraceptives were also tested on twenty-eight male and female psychiatric patients, which although acceptable by 1950s standards, would be viewed as unethical today.[75] After the initial trials in Boston, American researchers looked for a place where they could conduct larger trials; the researchers settled on the United States territory of Puerto Rico, where there were plenty of poor minorities they could exploit.[76]

> The women [in one Puerto Rican trial] had only been told that they were taking a drug that prevented pregnancy, not that this was a clinical trial, that the Pill was experimental or that there was a chance of potentially dangerous side effects. [Scientist Gregory] Pincus and [obstetrician and gynecologist John] Rock, however, believed they were following the appropriate ethical standards of the time. In the 1950s, research involving human subjects was much less regulated than it is today. Informed consent standards were minimal and only the most basic toxicity tests were required for human trials.[77]

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research. *Id.* at 27.

70. *Id.* Even if given consent forms, many of the prisoners were illiterate and could not understand them. *Id.* Consent forms included technical phrases like "'liver function measures.' 'I couldn't even understand them,' says Weitzman [a doctor]. 'How would an uneducated inmate?'" *Id.*

71. *Id.* at 37.

72. Abdullahi v. Pfizer, 562 F.3d 163, 168 (2d Cir. 2009).

73. *See People & Events: The Boston Pill Trials*, PBS, http://www.pbs.org/wgbh/amex/pill/peopleevents/e_boston.html (last visited Oct. 3, 2011).

74. *Id.*

75. *Id.*

76. *People & Events: The Puerto Rico Pill Trials*, PBS, http://www.pbs.org/wgbh/amex/pill/peopleevents/e_puertorico.html (last visited Oct. 19, 2011).

77. *Id.*

A final example of researchers taking advantage of minority populations was only exposed in late 2010.[78] In this venereal disease study, American doctors infected almost seven hundred inmates in Guatemala.[79] American doctors used "prison inmates, mental patients and soldiers" as the test subjects whom they injected with sexually transmitted diseases (STDs) and upon whom they "test[ed] the effectiveness of penicillin."[80] Susan Reverby unearthed the Public Health Service's (PHS) studies that took place in Guatemala between 1946 and 1948.[81] PHS researchers used infected prostitutes to have intercourse with study participants and infect them with STDs.[82] Researchers inoculated other participants with tissue from humans or animals infected with syphilis.[83] The researchers administered penicillin once they were satisfied with the amount of information collected from the subject.[84] Secretary of State Hillary Rodham Clinton and Health and Human Services Secretary Kathleen Sebelius immediately issued an apology to Guatemala, as well as study survivors and their descendants.[85]

The aforementioned studies are just a small sample of the manipulation of minorities that has occurred in clinical research in the past.[86] The ability of researchers to exploit inmates and working men shows that particular attention needs to be paid to disadvantaged groups. Requiring researchers to be competent in cultural distinctions can help to protect those populations.[87]

2. Minority Response

Due to the dark history of manipulation in clinical trials, many minorities are still reluctant to take part in clinical trials.[88]

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78. Donald G. McNeil, Jr., *U.S. Apologizes for Syphilis Tests in Guatemala*, N.Y. TIMES, Oct. 2, 2010, at A1.

79. *Id.*

80. *Id.*

81. Susan M. Reverby, *"Normal Exposure" and Inoculation Syphilis: A PHS "Tuskegee" Doctor in Guatemala, 1946–48*, 23 J. POL'Y HIST. 6, 6–9 (2011).

82. *Id.* at 13–15.

83. *Id.*

84. *Id.* at 17.

85. McNeil, *supra* note 78.

86. *See, e.g.*, WAYNE D. LEBARON, AMERICA'S NUCLEAR LEGACY 99–100 (1998) (describing radiation experiments that were carried out on poor cancer patients for eleven years, the majority of whom were Black).

87. *See* Virk, *supra* note 1.

88. *See* Amanda Gardner, *Black Americans Still Wary of Clinical Trials*, U.S. NEWS & WORLD REP. (Jan. 14, 2008), http://health.usnews.com/usnews/health/healthday/080114/black-americans-still-wary-of-clinical-trials.htm.

There is a lot of mistrust, especially in Black communities, of clinical trials and researchers.[89] This result is problematic because inclusion of a diverse population sample is imperative to achieving complete test results and applying them to different segments of the population.[90]

One of the main barriers to getting minorities to participate is a lack of knowledge about the process of clinical research.[91] Other barriers include "financial issues [and] lower rates of referrals to research protocols from clinicians."[92] It is not solely a reluctance of minorities to participate; occasionally there are external factors influencing participation.[93] For example, "pharmaceutical companies sometimes discourage the recruitment of diverse subject populations."[94]

Moving forward, policies and strategies must be developed to increase minority participation and achieve more equal representation in clinical research.[95] It is especially important because research has found that Blacks suffer from certain health problems at a higher rate than Whites.[96] Further, without increased minority participation in research, "exacerbat[ed] trends of poorer minority health" could result.[97] The history of mistreatment of minorities in clinical trials has revealed ways to protect patients and clinical trial participants.[98] Researchers can

89. *See* Killien et al., *supra* note 43, at 1064 ("In communities of color, past injustices and exclusion from the health professions have created explicit feelings of distrust. Some patients are reticent to make decisions about diagnostic strategies and treatment without discussing the decision with family and friends."); Gardner, *supra* note 88 ("Black Americans continue to distrust medical research and clinical trials, apparently a lasting legacy of the infamous Tuskegee experiment which was shut down more than three decades ago, a new study shows.").

90. *See* Svensson, *supra* note 39, at 263.

91. *See* Killien et al., *supra* note 43. Compounding the problem is the fact that minority populations are "vulnerable to exploitation." Noah, *supra* note 26, at 224.

92. Noah, *supra* note 26, at 225.

93. *Id.* at 227.

94. *Id.*

95. *See id.* at 224 ("[T]he research community must proceed with caution in any efforts to equalize participation, both because of the inherent risks of medical research to individual participants and because some efforts at racial inclusion may have unintended negative consequences."); Svensson, *supra* note 39, at 263.

96. Noah, *supra* note 26, at 223 (asserting that Blacks have a higher rate of complications from diabetes and certain cancers). This phenomenon also occurs in some other minority populations besides Blacks. *See id.*

97. *Id.* at 225.

98. *See* 44 Fed. Reg. 30,644 (May 25, 1979) ("By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees."); THE NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, DHEW PUBLICATION NO. (OS)

overcome the chasm created by bad clinical trials of the past by increasing diversity in current clinical trials.[99] The present lack of inclusion hinders complete medical research and can only be overcome by including minorities in trials. However, attempting to include minorities is not enough. Special attention needs to be paid to how culture will affect a potential participant's willingness to participate.

C. Laws and Ethics Codes To Prevent Unethical Experimentation

The Nuremberg Code[100] was promulgated as a result of unethical experiments performed on concentration camp prisoners.[101] The Nuremberg Code supplies a number of ethical principles for researchers to abide by.[102] One of the main focuses of the Nuremberg Code is the necessity of receiving voluntary consent from participants.[103] The Nuremberg Code was made in an attempt to prevent further unethical research on human subjects, but it was not a law.[104] Therefore American researchers were not *required* to abide by it, and in fact, some did not.[105]

The Declaration of Helsinki is a more recently drafted code of ethics that also does not have legal force, but sets out ethical principles for research.[106] The Declaration emphasizes researchers' duty to consider the health and well-being of their patients, as well as the necessity of voluntary and informed participation.[107] Both ethical codes inspired Title 45, Part 46 (Protection of Human

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87-0012, BELMONT REP. (1979) [hereinafter PROT. OF HUMAN SUBJECTS]. The Belmont Report was initiated just after the Tuskegee Study and established basic ethical guidelines and principles concerning studies on human subjects. *See* PROT. OF HUMAN SUBJECTS, *supra*.

99. *See* Svensson, *supra* note 39, at 265 (arguing that clinical trials will have greater accuracy and yield more meaningful results if there is increased minority participation in clinical drug trials).

100. Office of Human Subjects Research, *Regulations and Ethical Guidelines, Nuremberg Code*, NAT'L INSTS. HEALTH, http://ohsr.od.nih.gov/guidelines/nuremberg.html (last visited Oct. 19, 2011).

101. *People & Events: The Nuremberg Trials*, PBS, http://www.pbs.org/wgbh/amex/nuremberg/ (last visited Oct. 19, 2011).

102. *See* Office of Human Subjects Research, *supra* note 100.

103. *Id.*

104. *See* HORNBLUM, *supra* note 61, at 234.

105. *Id.* at 234–36.

106. *See* WORLD MED. ASS'N, DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2008), *available at* http://www.wma.net/en/30publications/10policies/b3/17c.pdf.

107. Office of Human Subjects Research, *Regulations and Ethical Guidelines: World Medical Association Declaration of Helsinki*, NAT'L INSTS. HEALTH, http://ohsr.od.nih.gov/guidelines/helsinki.html (last modified Sept. 10, 2004).

Subjects) of the United States Code of Federal Regulations.[108] The Declaration is still considered extremely important and relevant. "[T]he World Medical Association's Declaration of Helsinki . . . sets forth ethical principles to guide physicians world-wide and provides that human subjects should be volunteers and grant their informed consent to participate in research."[109]

> [The Declaration] enunciate[s] standards for obtaining informed consent from human subjects. It provide[s] that in clinical research combined with professional care, "[i]f at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation," and that non-therapeutic clinical research on a person "cannot be undertaken without his free consent, after he has been fully informed."[110]

The Declaration's discussion of the necessity of informed written consent and ethical treatment of research participants gives it an important place in clinical research.[111]

II. Informed Consent

A. Background and Development

One of the first constructions of the theory of informed consent can be found in a 1957 case.[112] Initially it was discussed in jury instructions detailing a duty to disclose.[113] The doctrine

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108. *See* 45 C.F.R. § 46 (2009). Part 46, Protection of Human Subjects, is still in effect today. *Id.*

> [T]his policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

Id. § 46.101.

109. Abdullahi v. Pfizer, 562 F.3d 163, 175 (2d Cir. 2009) (citing the Declaration as an important factor in the development of the informed consent doctrine to help protect research participants).

110. *Id.* at 181.

111. *Id.* at 181–82.

112. Salgo v. Leland Stanford Jr. Univ. Bd. of Trs., 317 P.2d 170 (Cal. Ct. App. 1957); *see also* Cathy J. Jones, *Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-Fulfilling Prophecy*, 47 WASH. & LEE L. REV. 379, 388–89 (1990).

113. *Leland Stanford Jr. Univ. Bd. Of Trs.*, 317 P.2d at 181 (explaining a doctor's duty to explicate all important facts to patients so they can "form the basis of intelligent consent . . . to the proposed treatment").

continued to develop over the years.[114] The American Medical Association currently defines informed consent as "[the] process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention."[115]

B. Requirements and Exceptions

"Most consent cases generally focus on whether the consent was 'informed,' i.e., whether the patient was given sufficient information to make a decision regarding his or her body and health care."[116]

The general requirements of what information must be given to patients for valid informed consent for regular medical treatments include the "problem or diagnosis for which further investigation or intervention is proposed, . . . the recommended intervention . . . with the significant benefits and risks [involved], the results or prognosis if no intervention is attempted, and . . . any significant alternative[s] . . . ."[117] It is also a requirement that informed consent be documented on a written consent form.[118]

Three exceptions to gaining informed consent from competent patients can be applied: waiver, emergency, and therapeutic privilege.[119] Waiver, which focuses on autonomy, gives patients the right to forego "their right to give . . . informed consent," with the requirement that waiver is voluntary and intentional.[120] The emergency exception is fairly self-explanatory; if there is an emergency "a doctor may render treatment without the patient's consent; consent is said to be implied."[121] Therapeutic privilege is the most well-known exception, applying in a situation in which informing the patient could somehow cause harm to the patient.[122]

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114. Jones, *supra* note 112, at 389–96.

115. *Patient Physician Relationship Topics: Informed Consent*, AM. MED. ASS'N, http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.shtml (last visited Sept. 22, 2011).

116. *Id.*

117. STEPHEN WEAR, INFORMED CONSENT: PATIENT AUTONOMY AND CLINICIAN BENEFICENCE WITHIN HEALTH CARE 10 (1998); *see* 21 C.F.R. § 50.23 (2011).

118. 21 C.F.R. § 50.27.

119. *See* JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 75–125 (2d ed. 2001).

120. *Id.* at 85.

121. *Id.* at 76.

122. *See id.* at 79. For example, suppose a doctor withholds from the patient the medical name for an illness because of the stigma attached to it. "Insisting that [the] patient hear the name of [the] condition, at the likely cost of failing to ensure that [he/]she understands what [he/]she needs to do to help improve [his/]her

Consent must be obtained if feasible.[123] It is considered unfeasible if it can be certified in writing that four provisions apply: it is a life threatening situation; the patient is unable to communicate; there is insufficient time to obtain consent from the patient's legal representative; and there are no approved or generally recognized alternative therapies to save the patient's life.[124] The concept of informed consent is also codified in statutes.[125]

Other regulations provide that informed consent must be obtained from each research participant and the participant must have an "[o]pportunity to consider whether or not to participate" in the research.[126] In addition, the researchers have to "minimize the possibility of coercion or undue influence" of the research participants.[127] It is well accepted that if a study participant speaks a language other than English, information must be given in the language the participant speaks and understands.[128] If the information is given to the participant in a language he or she understands, the requirements of informed consent have been satisfied.[129] There are, however, other factors to be considered.[130]

C. *Cultural Beliefs, Informed Consent, and Clinical Research*

As stated above, researchers continue to encounter difficulty recruiting minorities and diverse populations for clinical research

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situation, would be harmful." Matthew Wynia, *Invoking Therapeutic Privilege*, VIRTUAL MENTOR, Feb. 2004, *available at* http://virtualmentor.ama-assn.org/2004/02/msoc1-0402.html.

123. 21 C.F.R. § 50.23.

124. *Id.*

125. *See, e.g.*, 21 U.S.C. § 355 (2006). Section 355 reads:

> [R]equiring that experts using . . . drugs for investigational purposes certify . . . that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings.

Id.

126. 21 C.F.R. § 50.20 (2011).

127. *Id.*

128. *See id.*

129. *See id.*

130. For example, the patient's health literacy should be considered. A problem with the approach of only requiring provision of information in a patient's language, is that an "individual's ability to read and comprehend health-related materials, such as medication instructions and informed consent forms, may be substantially weaker than [his or her] general literacy." Noah, *supra* note 26, at 228.

studies. First, a lack of trust of researchers and a low understanding of the process creates a barrier to reaching diverse populations.[131] Also, language barriers make it more difficult for researchers to give notice to minority communities as researchers seek to diversify studies.[132] Finally, researchers are less inclined to include populations with language barriers because of the need for translators and interpreters, along with the difficulties in following-up with participants.[133]

The focus of this Article is on the lesser known cultural aspects involved with including minorities in clinical research. "Cultural differences . . . lead to miscommunication and misinterpretation of actions and motives, among both potential study participants and investigators."[134] Many minority groups have differing views on health care and its specific role in their culture.[135] For example, in the Hispanic community, family is extremely important, as are respect and personal relationships.[136] Additionally, Hispanic communities embrace concepts such as *espiritismo* and *fatalismo*.[137] Other variations are seen in the Hmong population.[138] The Hmong have a culture in which shamans are very important and the language has few medical terms; they believe in spiritual healings and herbal treatments.[139] Many Ethiopians believe in a strong connection between "the body and the outside," often attributing illnesses to an exterior cause.[140]

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131. *See* Killien et al., *supra* note 43; *supra* Part I.B.ii.

132. *See* Janet D. Stemwedel, *Language Barriers and Human Subjects Research*, ADVENTURES ETHICS & SCI. (Feb. 23, 2009, 7:08 PM), http://scienceblogs.com/ethicsandscience/2009/02/language_barriers_and_human_su.php.

133. E-mail from Sara DeSanto, *supra* note 8.

134. Killien et al., *supra* note 43.

135. *See* Robert J. Blendon et al., *How White and African Americans View Their Health and Social Problems*, 273 JAMA 341, 341 (1995).

136. Ross Mullner & Aida L. Giachello, *Traditional Health and Disease Beliefs, Access to Health Care, Cultural Sensitivity*, HEALTH, http://www.jrank.org/cultures/pages/3951/Health.html (last visited Sept. 20, 2011) (archival version on file with author but no longer available on the Internet).

137. *Id.* *Espiritismo* is described as "view[ing] health synergistically as a continuum of mind, body, and espirtu (spirit). Illness symptoms are derived from this continuum. Mental health problems and psychosocial stress are likely to appear as somatic complaints." *Id.* *Fatalismo* is the belief "that disease is a punishment sent by God . . . for wrongdoings. Therefore, many Hispanics believe that suffering from a disease must be accepted and endured by the individual." *Id.*

138. *See* STRATIS HEALTH, CULTURE MATTERS: INFORMATION ON HMONG CULTURE AND HEALTH CARE 2 (2006), *available at* http://www.stratishealth.org/documents/CC_Hmong_121907.pdf.

139. *Id.* at 1–2.

140. Richard M. Hodes, *Cross-Cultural Medicine and Diverse Health Beliefs: Ethiopians Abroad*, 166 W. J. MED. 29, 29 (1997).

These few examples illustrate how views of health care can differ between cultures. Understanding the differences is imperative in clinical research as well as in implementing successful health care.[141] Although cultural nuances have yet to be addressed in clinical research, steps have been taken to avoid unethical and unjust treatment.[142]

III. Laws and Policies To Increase Minority Inclusion and Ethical Treatment

A. *National Research Act and the Belmont Report*

The National Research Act was passed in 1974 and created the National Commission for the Protection of Human Subjects of Biomedical Research.[143] The Commission sought to avoid replicating past injustices in human experimentation by identifying ethical principles to guide future researchers.[144] A few years later, the Belmont Report was created, compiling the Commission's findings.[145] The Belmont Report is a policy statement created after careful thought by eleven legal, medical, and ethical professionals.[146] "It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects."[147]

B. *National Institutes of Health*

The National Institutes of Health (NIH) is an agency that sponsors and funds clinical trials.[148] "NIH is the largest source of funding for medical research in the world . . . ."[149] NIH is "a part of the U.S. Department of Health and Human Services," and is

141. *See* Jacquelyn C. Campbell et al., *Challenges of a Multisite Multicultural Collaborative Research Endeavor: The Birthweight Study*, *in* DIVERSITY IN HEALTH CARE RESEARCH: STRATEGIES FOR MULTISITE, MULTIDISCIPLINARY, AND MULTICULTURAL PROJECTS 145, 147 (Joellen W. Hawkins & Lois A. Haggerty eds., 2003) (showing the cultural aspect is important because it is "crucial if the outcome is to lead to knowledge that guides the provision of culturally competent care").

142. *See infra* Part III.

143. *The Belmont Report*, HHS.gov, http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html (last visited Oct. 2, 2011).

144. *Id.*

145. PROT. OF HUMAN SUBJECTS, *supra* note 98.

146. *The Belmont Report*, *supra* note 143.

147. *See id.*

148. *Understanding Clinical Trials*, *supra* note 21.

149. U.S. Dep't of Health & Human Servs., *About the National Institutes of Health*, NIH.GOV (Oct. 27, 2010), http://www.nih.gov/about/index.html.

comprised of "27 Institutes and Centers, each with a specific research agenda . . . ."[150] The NIHRA was passed in 1993.[151] Through this Act, Congress "made what had previously been policy into public law."[152] The Act provided four important additions to the NIH policies that were in place at the time:

- NIH ensures that women and minorities are included in all human subject research;
- Phase III clinical trials[']] inclusion of Women and minorities in numbers adequate to allow for valid analyses of differences in intervention effect;
- Cost is not allowed as an acceptable reason for excluding these groups; and,
- NIH initiates programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as volunteers in clinical studies[.][153]

The following year, NIH "published [the] NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research in the Federal Register."[154] The NIH developed these guidelines as a response to the requirements of the NIHRA.[155] The outreach notebook includes factors to consider when including minorities in clinical research and discusses the necessity of understanding minority populations.[156]

C. FDA

The Investigational New Drug Application section of the Code of Federal Regulations enables the FDA to review the applications for investigational new drugs (INDs).[157] The FDA has made efforts to increase minority participation in clinical research.[158] "[T]he Food and Drug Modernization Act of 1997

150. *Id.*

151. National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 289a-2 (2006).

152. Nat'l Insts. of Health, *Inclusion of Women in Research*, OFF. RES. ON WOMEN, http://orwh.od.nih.gov/inclusion.html (last visited Oct. 2, 2011).

153. *Id.*

154. NAT'L INSTS. OF HEALTH, OUTREACH NOTEBOOK FOR THE NIH GUIDELINES ON INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH 1 (1994) [hereinafter NIH GUIDELINES].

155. *Id.*

156. *See id.* at 3. Some of the factors include "characteristics of the population of interest and the settings in which they are encountered." *Id.* at 1.

157. 21 C.F.R. § 312.1 (2010).

158. B. Evelyn et al., *Participation of Racial/Ethnic Groups in Clinical Trials and Race-Related Labeling: A Review of New Molecular Entities Approved 1995–1999*, 93 J. NAT'L MED. ASS'N 18S, 19S (2001) ("Attention to potential racial and ethnic differences in response to drugs is part of a larger effort by the FDA to

(FDAMA) . . . prompted [the] FDA to examine issues related to the inclusion of racial and ethnic groups in clinical trials."[159] FDAMA "called for the establishment of a clinical trials registry that would be available to the public," leading to the creation of the "ClinicalTrials.gov" website.[160] The FDAMA also instructs the FDA to consult with the NIH and other industry members for guidance to achieve the goal of including more women and minorities in clinical trials.[161]

These policies and regulations are a good starting point for ethically conducted research that is inclusive of diverse populations. However, carefully planned legislation can help ease the difficulties of including diverse populations and moving past cultural barriers.

IV. Suggested Solutions for Clinical Research Legislation

A. Problems with the Current Approach

Currently, no laws specifically require minorities to be included in all clinical research.[162] Furthermore, legislation and guidelines do not address the *cultural* differences that play an important role for many minority populations.[163] Although there are regulations and laws in place that encourage or require participation, loopholes allow researchers to avoid the requirement of including minorities in their research.

The NIHRA is an example of seemingly complete legislation that contains loopholes that allow manipulation.[164] One provision

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ensure that the safety and efficacy of drugs are adequately studied in people who represent the full range of patients who will receive them upon marketing.").

159. *Id.*

> Section 505(b)(1) (21 U.S.C. 355(b)(1)) is amended by adding . . . : "The Secretary shall, . . . with the Director of the [NIH] and with representatives of the drug manufacturing industry, review and develop guidance . . . on the inclusion of . . . minorities in clinical trials . . . ."

Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296.

160. Mary Fitzgerald, *Advocate for Access to Medical Data: Linguist Wants Patients To Understand*, WASH. POST, July 28, 2004, at A17.

161. Richard A. Merrill, *Modernizing the FDA: An Incremental Revolution*, 18 HEALTH AFF. 96, 100 (1999), *available at* http://content.healthaffairs.org/content/18/2/96.full.pdf.

162. *See* National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 289a-2 (1993); 111 Stat. 2296. Neither the NIH Revitalization Act nor the Food and Drug Administration Modernization Act require minorities to be included in all clinical studies. *See* 42 U.S.C. § 289a-2 (1993); 111 Stat. 2296.

163. *See, e.g.*, 111 Stat. 2296 (failing to include cultural differences in its requirements for clinical trials).

164. *See* 42 U.S.C. § 289a-2.

contains an exception stating that minorities do not have to be included if the researchers can show that there would be no *significant* difference between the results the researchers would obtain from a minority participant and the participants they plan to include.[165] However, it might be difficult for a researcher to show that the variables will not impact the races differently if they are researching a novel condition, disease, or medication.[166]

If researchers are making relatively minor changes to the medication or treatment, and before those changes, insignificant differences resulted among the races, it still could be useful to know how the new changes would differently impact various subsets of the population. To obtain that information, minorities should be included in the research and cultural differences should be a factor used in communicating with participants, conducting the research, and applying the results.[167]

Regulators must strike a balance. Though clinical researchers should retain the ability to comply with the NIHRA, loopholes that automatically qualify clinical research as suitable should be eliminated.[168] Unless specifically tailored to a certain race, clinical researchers should be encouraged to include a variety of cultures in their clinical research, no matter how similar they think the results might be.[169]

Additionally, clinical researchers often incorrectly equate the inclusion of minorities with cultural variety.[170] Many different cultures can exist within one minority population.[171] Differences in medical practices, family roles, and other factors such as what each culture perceives as an illness exist in different minority cultures.[172] The lack of consideration and legislation directing researchers to consider these factors can make it more difficult for

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165. *Id.* § 289a-2(d)(2)(B).

166. *See* Mayo Clinic Staff, *Clinical Trials: A Chance To Try Evolving Therapies*, MAYOCLINIC.COM (July 2, 2011), http://www.mayoclinic.com/health/clinical-trials/DI00033. The purpose of clinical trials is to test new medications or research new diseases to learn more about them. *See id.*

167. *See* Campbell et al., *supra* note 141.

168. *See* 42 U.S.C. § 289a-2(d)(2)(B).

169. *See, e.g.*, Deborah S. Smith et al., *Racial Differences in a Prostate Cancer Screening Study*, 156 J. UROLOGY 1366, 1366 (1996) (stating results of a study of White and Black men showed that Black men had a less than two percent higher chance of prostate cancer).

170. *See* Campbell et al., *supra* note 141 ("Investigators need to give serious consideration to the role of cultural factors and avoid assuming that identity with the minority culture is defined by the person's race or surname.").

171. *See* Leonard E. Egede, *Race, Ethnicity, Culture, and Disparities in Health Care*, 21 J. GEN. INTERNAL MED. 667, 667 (2006).

172. *See* Mullner & Giachello, *supra* note 136.

researchers to connect and build trust with participants.[173] The FDA has the right end goal in mind: to encourage adequate minority participation.[174] However, a greater understanding of minority cultures is also necessary for successful and more complete research.[175] There are some enrollment issues, in part because of the role culture plays in a potential participant's decision-making.[176] Once the medical community acquires a proper understanding of cultural factors' influences, physicians will be better able to understand how to effectively treat their patients.

B. Cultural Focus in Clinical Research Participants

Currently there is a lack of legislation focused on the cultural aspects of participants in clinical trials.[177] Cultural differences can lead to different results with medications or illnesses,[178] but the lack of legislation and regulations addressing these variables allows clinicians to ignore such factors. A difference in culture can affect how participants and the public view doctors and medicine.[179] Foundational beliefs greatly affect medical application, and truly make a difference. The Chaplain involved in a case where a pregnant woman from Central America was diagnosed with leukemia said that:

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173. *See* WASHINGTON, *supra* note 65.

174. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296.

175. Campbell et al., *supra* note 141.

176. *See* WASHINGTON, *supra* note 65, at 180 (discussing "African Americans' aversion to the health-care system"). Blacks are still reluctant to participate due to the history of Blacks in the health care system: "a centuries-old pattern of experimental abuse . . . ." *Id.* at 180–81.

177. *Regulations*, FDA (Nov. 26, 2010), http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/ucm155713.htm. The FDA's website lists laws and regulations surrounding clinical trials, and none of them contain requirements of consideration of cultural factors. *Id.* Only three states have enacted mandatory legislation: California, New Jersey, and Washington. Mary Nakashian, *Studying State Legislation of Cultural and Linguistic Competence*, ROBERT WOOD JOHNSON FOUND. (Oct. 2009), http://www.rwjf.org/reports/grr/059024.htm.

178. *See* Interview with Ralph Hall, Teaching Specialist, Univ. of Minn. Law Sch., in Minneapolis, Minn. (Oct. 20, 2010). This can occur because some cultures will not take medication as prescribed or will use different treatments for illness. *Id.* If a researcher has an understanding of this occurrence, he or she can tailor the research process when necessary to increase the likelihood of accurate results. *Id.*

179. *See, e.g.*, WASHINGTON, *supra* note 65, at 180 ("The Tuskegee Syphilis Study ended a quarter of a century ago, but its effects can still be felt. . . . 'Many African Americans' distrust in today's medical establishment can be attributed to Tuskegee.'" (quoting Deborah Shelton, *Mistrust of Doctors Lingers After Tuskegee; Many Blacks Remain Wary—and Underserved—a Quarter Century After Infamous Syphilis Study*, WASH. POST, Apr. 15, 1997, at Z8)).

> [W]e could have done a better job [from a cultural perspective] . . . . We're talking about foundational beliefs and about comfort—not the medical comfort, but comfort with the space, the presence, the people. Think about if we were receiving our end-of-life care in [Latin America], surrounded by Spanish-speaking people . . . .[180]

Because of such differences, some cultures might be excluded or tend to self-exclude themselves from clinical research.[181] For example, breast cancer mortality is higher among Black women than White women, yet the "incidence [of breast cancer] is somewhat lower among [Black] women."[182] Socioeconomic factors influence when patients receive medical attention for breast cancer, but "[c]ultural factors such as beliefs, attitudes, and knowledge about cancer are also known to vary dramatically by race, and the importance of these cultural factors is increasingly recognized."[183] Lannin's breast cancer study determined that some of the cultural factors that influenced at which stage breast cancer patients were diagnosed included "health care utilization, folk beliefs, relationships with men, perceived risk or fatalism, [and] belief in various treatments . . . ."[184] The same phenomenon translates into clinical trials as well; cultural factors will impact medical diagnoses and presentation of symptoms, side effects, patient comfort and drug reactions.[185] Also, with different cultures, especially when a participant speaks a foreign language, patients' perception of autonomy might be skewed.[186]

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180. Alexander K. Smith et al., *Palliative Care for Latino Patients and Their Families*, 301 JAMA 1047, 1048 (2009).

181. *See* WASHINGTON, *supra* note 65, at 180. Many Blacks still distrust doctors and medical establishments due to the negative history, resulting in many Blacks self-excluding. *See id.*

182. Donald R. Lannin et al., *Influence of Socioeconomic and Cultural Factors on Racial Differences in Late-Stage Presentation of Breast Cancer*, 279 JAMA 1801, 1801 (1998).

183. *Id.* (citation omitted).

184. *Id.* at 1804. Furthermore, "[w]omen who held any of the culturally derived folk beliefs, fundamentalist religious beliefs, or beliefs about relationships with men or fatalism were all significantly more likely to present with late-stage disease." *Id.*

185. *See* Interview with Ralph Hall, *supra* note 178.

186. *See* Andrew Fagan, *How Autonomous Is Medical Decision Making?*, 11 AM. MED. ASS'N J. ETHICS 631, 633–34 (2009).

> The more deeply an individual is formed by . . . culture, the more difficult it will be to recreate his or her identity in an alternative existential setting. The depth of an individual's integration within some communities and the absoluteness of that community's ethical prescriptions can severely restrict the individual's capacity to exercise choice . . . .

Id.

Legislation addressing cultural factors in clinical research can allow the participant and researcher to lower the barriers to entry.[187] The consideration of cultural factors will eventually become a necessity due to the changing cultural makeup of the United States.[188] FDAMA and NIHRA are the first steps in addressing the inclusion of minorities in clinical research.[189] Attributing various reactions and disease prevalence rates to certain races and ethnicities is crucial to properly addressing clinical research and interpreting results.[190] Furthermore, determining the risk factors for certain diseases that are associated with particular racial or ethnic groups can enable the medical community to better-tailor health care for individual patients.[191]

Cultural beliefs greatly impact how a person interprets symptoms.[192] Without considering cultural identity in research studies, it is possible that researchers will overlook factors imperative to their research or will misinterpret results.[193] For example, symptoms might manifest themselves differently due to varied cultural interpretations of what a symptom represents, risking misinterpretation of results.[194]

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187. *See* Campbell et al., *supra* note 141. "Some reliable and valid means of assessing subjects' degree of identification with their own culture greatly enhances the research. Assessing the role of factors such as assimilation, country of origin, and migratory status is important." *Id.*

188. *See U.S. Minorities Will Be the Majority by 2042, Census Bureau Says*, AMERICA.GOV (Aug. 15, 2008), http://www.america.gov/st/diversityenglish/2008/August/20080815140005xlrennef0.1078106.html.

189. *See* National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 289a-2 (2006); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296.

190. *See* Ctrs. for Disease Control & Prevention, *General Refugee Health Guidelines*, CDC.GOV (Aug. 23, 2010), http://www.cdc.gov/immigrantrefugeehealth/guidelines/general-guidelines.html. For example, Hmong have a higher prevalence of gout. *See* Interview with Ralph Hall, *supra* note 178.

191. *See* WASHINGTON, *supra* note 65, at 314–15. "[B]lack women . . . have a higher-than-normal risk of the $BRCA_1$ gene, which confers as much as a 70 percent higher risk of breast cancer . . . ." *Id.* "African Americans and Hispanics living in Manhattan . . . harbor a genetic variant (APOE-epsilon$_4$) that places them at a higher relative risk of developing Alzheimer's disease than [W]hites." *Id.* at 315 (citations omitted). Some of the factors can be extremely important for clinical studies, such as in the case of "African Americans . . . [being] more likely than [W]hites to be healthy carriers of glucose-6-phosphate dehydrogenase (G6PHD) syndrome, which can cause the loss of red blood cells and affects many medical risks and medication reactions." *Id.* (citations omitted).

192. Campbell et al., *supra* note 141, at 151.

193. *See id.*

194. *Id.*

> [T]he list of symptoms . . . and interpretations associated with it are attempts to capture and categorize . . . ways that people experience or

> Recognizing that a lump is growing and becoming bothersome . . . does not necessarily imply that a woman will seek medical treatment for it. The majority of patients with late-stage presentation believed that "letting air get to a cancer" or "cutting on a cancer" was to be avoided because it would cause the cancer to spread. Instead, many advocated the use of alternative treatments . . . prayer and a reliance on God to heal the disorder.[195]

If a patient or participant is afraid of discussing or exposing symptoms he or she is experiencing, it can become a danger to the health of the patient or participant.[196]

Safety and dialogue are primary concerns for researchers understanding how different cultures interpret symptoms.[197] Requiring researchers to use translators and interpreters is a first step to achieving cultural variety.[198] Occasionally, however, relevant information is lost in translation.[199] "Language fluency is not a yes-or-no skill but a spectrum that includes facility of language, familiarity with medical terminology, and understanding of cultural context. An imbalance between speaking ability and understanding may lead to situations in which clinicians can ask simple questions in Spanish, but not understand complex responses."[200] This leads to the question, what are researchers "excluding such that risks and benefits are difficult to determine for the population?"[201] Excluding important cultural nuances in clinical research could lead to negative or problematic reactions to the product.[202] Though translation and interpretation are imperative for clinical research, other cultural factors must be considered as well.[203]

> report their experience. The experiences on which most instruments are based are usually of . . . Euro-American origin . . . . [D]ifferent experiences and different languages may engender different manifestations of distress or wellness.

Id.

195. Lannin et al., *supra* note 182, at 1806.

196. Eunice Kennedy Shriver, Nat'l Inst. of Child Health & Human Dev., *What Else Should I Know About Clinical Research?*, NAT'L INSTS. HEALTH (June 24, 2010), http://www.nichd.nih.gov/health/clinicalresearch/aboutclinicalresearch.cfm.

197. *See* Campbell et al., *supra* note 141, at 151.

198. *Understanding Clinical Trials*, *supra* note 21.

199. Killien et al., *supra* note 43.

200. Smith, *supra* note 180, at 1050.

201. Interview with Ralph Hall, *supra* note 178.

202. *Id.*

203. Killien et al., *supra* note 43 (supporting the opinion presented in this Article that translation itself does not accomplish the necessity of adequate inclusion of minority populations).

The perception of power is another important factor when approaching cultural differences. Cultural norms and power hierarchies are an important aspect of cultural familiarity.[204] Sometimes decision-making power resides with the individual, while other times it is with family members or other community members.[205]

A further consideration when addressing patient care, especially in clinical trials, is cultural autonomy.[206] How much a participant identifies with his or her culture should determine how to approach that patient.[207] A particular study participant might not identify with all aspects of his or her culture, which could mean culture has less of an impact on his or her participation in the study.[208] If a person identifies closely with his or her culture, how much autonomy does he or she have?[209] Some questions might be: whether or not he or she makes his or her own medical decisions; how other decisions are made within his or her culture; the importance of family; and in some cases, the male and female power relationship.[210] If researchers know what questions to ask and what patients view as important, they will be able to better communicate with patients and therefore obtain more accurate results.[211]

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204. *See* Hispanic Healthy Marriage Initiative, *Gender Norms and the Role of the Extended Family*, DEP'T HEALTH & HUMAN SERVICES ADMIN. FOR CHILD. & FAMS. 2, http://www.acf.hhs.gov/healthymarriage/pdf/Gender_Norms.pdf (last visited Oct. 2, 2011). Historically, in Hispanic families, men hold control while women tend to be more submissive; extended family is seen as very important. *Id.* Although these are seen as the traditional roles and still impact many relationships, this generalization should not be made to all families today. *Id.*

205. *See, e.g.*, Smith et al., *supra* note 180, at 1054 (stating that in the Hispanic community, women are responsible for health issues within their families).

206. *See* Interview with Ralph Hall, *supra* note 178. "Legal scholars define cultural autonomy as 'the right to self rule, by a culturally defined group, in regard to matters which affect the maintenance and reproduction of its culture.'" STEVEN C. ROACH, CULTURAL AUTONOMY, MINORITY RIGHTS, AND GLOBALIZATION 3 (2005).

207. *See* Sylvestre Quevedo, *Culture and Medicine: Reflections on Identity and Community in an Age of Pluralism*, PERMANENTE J., Winter 2008, at 63, 64–65. Quevedo gives a definition of culture "as 'a shared system of values, beliefs, and learned patterns of behavior.'" *Id.* at 64 (citations omitted).

208. *See id.* This could be equated with religion; not every person identifies or agrees with every single tenet of his or her religion. Quevedo, quoting Jerome Bruner, puts it sensibly: "to be part of a culture is to be 'bound in a set of connecting stories, connecting even though the stories may *not* represent a consensus.'" *Id.* (emphasis in original) (citations omitted).

209. *Id.* at 64–65.

210. *See* Mullner & Giachello, *supra* note 136.

211. *See* Campbell et al., *supra* note 141, at 151; Lowanda Dent, *The Role of Cultural Competency in Eliminating Health Disparities*, MINORITY NURSE, Winter 2005, at 52–55, *available at* http://www.minoritynurse.com/cultural-competency/role-cultural-competency-eliminating-health-disparities.

C. Suggesting New Legislation

To correct the inequality created by ignoring cultural factors in clinical research, legislation must be passed that can begin to remedy the problem. When the bill is proposed it must be considered carefully and in collaboration with agencies possessing necessary expertise. Agencies often possess the knowledge necessary to determine the importance of accounting for cultural variety in research.[212] Furthermore, some studies focus on a particular subset of the population by design, so legislation should be drafted to reflect this.[213] By including agency expertise in new legislation, it will help to make sure that legislation includes plausible changes as well as the crucial specificity.

1. Potential Language of New Legislation

The legislation drafted should include a provision stating that cultural factors must be considered. Researchers are often reluctant to include minorities in research because language barriers, comprehension problems, and other difficulties make researchers' tasks more complicated.[214] To ease compliance, the legislation should provide researchers with comprehensive guidance. Such guidance could include the factors that should be considered when addressing cultural competence and the sites that should be consulted in determining a culture's approach to medical care.[215]

While in an ideal world a variety of cultures would be included in every clinical research study, it is impracticable to require such uniform inclusion. Occasionally, a specific study will not necessitate inclusion of all minorities and cultural factors in research—for example researching how a medication will affect a particular race.[216] The legislation should reflect those exceptions, but be extremely specific so as not to create unnecessary loopholes. Careful thought should be given to the statute's list of exceptions

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212. *See* NIH GUIDELINES, *supra* note 154, at 25 (outlining federal agencies able to assist clinical investigators).

213. *See* Ranganathan & Bhopal, *supra* note 41, at 332 (discussing the history of studying "ethnic variations in disease").

214. *See* Stemwedel, *supra* note 132.

215. *See* NIH GUIDELINES, *supra* note 154, *passim* (discussing factors to be considered in including minorities and women in clinical experimentation).

216. *See* WASHINGTON, *supra* note 65, at 315 (discussing differences of medical conditions between certain races in Manhattan). If researchers wanted to specifically focus on a reaction that occurs in one race that has already been studied in a diverse environment, it would not necessitate including a diverse cultural makeup. *See* OUTREACH NOTEBOOK, *supra* note 4, at 22.

to avoid further problems such as the manipulation of ambiguities.[217]

Legislation requiring cultural consideration in clinical research will provide an avenue through which clinical researchers can ensure fairness and equality. Furthermore, this legislation will provide an impetus for researchers to become aware of cultural considerations. This awareness will eventually become second nature to researchers.[218] A further method of ensuring cultural factors are accounted for would be to have a cultural expert available to researchers. This expert could tell researchers necessary and pertinent information about the populations who are participating in their study.[219] An example of possible language incorporating these ideas is:

> When including various cultures in research, researchers must consider cultural factors and their impact on results by consulting a cultural expert or achieving cultural competency in another matter approved by the [FDA or NIH]. Researchers are not required to include an array of cultures if studying the impact of a medication or procedure on a specific subset of the population, or when following up on specific results within a population of a previous study that included a variety of cultures.

The cost of implementing this legislation is another concern. Time and money will be necessary for researchers to become culturally competent.[220] Due to the cost and current unstable economic conditions in the United States, such implementation will probably not be immediate.[221] However, the sooner steps are taken to implement these changes and require incorporation of cultural factors, the sooner that better and more accurate results can be expected.

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217. *See supra* Part IV.A. The exceptions in NIHRA do not provide enough specificity to avoid giving researchers the ability to comply with the Act while still excluding minorities. *See* National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 289a-2 (2006).

218. *Cf.* Killien et al., *supra* note 43, at 1068–69 (asserting that increased inclusion of "underrepresented groups" will improve understanding achieved through clinical research).

219. *Cf.* NIH GUIDELINES, *supra* note 154, at 14 (arguing that advisory boards can guide recruitment of individuals from certain cultures to clinical research studies).

220. Acquiring the knowledge will not happen immediately, but over time researchers can incorporate the ability to work cultural differences into their knowledge base. *See* Judith A. Lewis, *Foreword* to DIVERSITY IN HEALTH CARE RESEARCH, *supra* note 141, at xi (arguing that "learned knowledge, skills, and abilities" are critical to ensuring cultural sensitivity in clinical experimentation).

221. For example, Cohen, *supra* note 13, at 2, noted that "in 2005 the federal government spent about $1.5 billion on all health services research . . . ." This level of expenditure would be unlikely in today's economic climate.

2. Uniform State Laws Versus Federal Law

Legislation could be passed at the federal level, or a uniform law could be drafted for states to pass individually. Uniform laws are a model that states are encouraged to adopt individually. Once adopted, they become law in that state.[222] For a variety of reasons, state-by-state adoption of a model law is not the best direction to take the legislation.[223] Not every state will necessarily adopt a uniform law, which means states without the requirement of considering cultural factors in research could become the location of choice for researchers to get around the new requirements.[224] Additionally, because each state adopts and codifies the law itself, states can make individual changes to the law, destroying uniformity.[225] This would make it easier for a state health agency to oversee the enforcement and application of the law.

However, a model law would not be the proper approach to implementing the legislation. The Food and Drug Administration (FDA) oversees clinical trials. Thus, enforcement and application should be left to the federal agencies and federal legislature.[226] The risk of nonuniformity is too great. A model law would burden the FDA and NIH with having to consider separate and sometimes different standards for each state when reviewing clinical research.[227] Uniformity and requiring all clinical researchers to abide by the same standards is imperative when implementing the requirement of considering cultural factors in clinical research.

Because the FDA has authority to oversee clinical trials and the NIH supports clinical trials, a federal law is needed.[228] A federal law would make it easier for the FDA to oversee clinical trials and ensure researchers are complying with the law. It would not make sense in this situation to give federal agencies responsibility for implementing individual state regulations in addition to any other federal laws to which the researchers might

222. *See* Duke Univ. Sch. of Law, *Uniform Commercial Code*, CORNELL U.L. SCH. (July 2011), http://www.law.duke.edu/lib/researchguides/ucc.

223. *See* Cornell Univ. Law Sch. Legal Info. Inst., *Uniform Laws*, CORNELL U.L. SCH., http://www.law.cornell.edu/uniform/ (last visited Oct. 2, 2011) [hereinafter *Uniform Laws*].

224. *See* Duke Univ. Sch. of Law, *supra* note 222.

225. *Id.*

226. *See* Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 379 (substantially recodifying the FDA's authority to govern clinical trials of drugs and medical devices).

227. *See Uniform Laws*, *supra* note 223.

228. 21 U.S.C. § 379.

be subject. This is an area that should continue to be entrusted exclusively to the federal government and its agencies.

Finally, uniformity provided by a federal law can serve as an example for researchers in other countries of how they can properly consider cultural factors. Other countries recognize the need to include minorities in clinical research and new legislation has the potential to have an international impact.[229]

3. Additional Considerations

From a policy standpoint, researchers and the legislature alike should include cultural aspects of minority populations as criteria to be considered in clinical trials.[230] After years of manipulation and abuse in clinical trials, wary minorities need to feel their safety will be a concern if they participate in trials.[231] Creating legislation that includes cultural differences is a way to assuage the fears of distrustful minorities.[232] When aiming to increase minority participation in clinical trials through legislation, Barbara A. Noah has explained the need to "proceed with caution . . . both because of the inherent risks of medical research to individual participants and because some efforts at racial inclusion may have unintended negative consequences."[233] Though the NIH has recognized that cultural diversity is important, more should and can be done to implement that knowledge.[234]

Furthermore, researchers could be incentivized to consider cultural variation among participants in their research.[235]

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229. *See, e.g.*, Mahvash Hussein-Gambles et al., *Why Ethnic Minorities are Underrepresented in Clinical Trials: A Review of the Literature*, 12 HEALTH & SOC. CARE COMMUNITY 382, 382 (2004) (noting that exclusion of minorities "undermines the UK government's National Health Service (NHS) plan for tackling inequalities, and its core principle of providing culturally appropriate and accessible care for different groups and individuals").

230. *See* WASHINGTON, *supra* note 65, at 386–88 (arguing that the untrustworthiness of American medical research decreases the participation of minorities and that laws have improved the situation, but that more needs to be done). Including cultural factors is a way to make minorities feel more at ease and trusting of clinical trials. *See id.* at 387.

231. *See* NIH GUIDELINES, *supra* note 154, at 12.

232. *See id.* (arguing that consultation between researchers and subjects can increase appreciation of important cultural differences).

233. Noah, *supra* note 26, at 224.

234. NIH GUIDELINES, *supra* note 154, at 8 ("[C]onsiderable heterogeneity can exist within health care settings and communities . . . . [C]ultural . . . characteristics can vary widely, along with major differences in health beliefs and practices. Recruitment and retention strategies must therefore be based on the background information about the particular groups of interest.").

235. Noah, *supra* note 26, at 232. Noah suggests incentivizing pharmaceutical

Researchers, however, should not have to be incentivized to do something that will positively help them and their participants. The importance of cultural differences should not continue to be ignored, especially when an effort is being made to include minorities in clinical research.[236] A comprehensive clinical research law will allow minorities to be included and given a voice.

Conclusion

The history of clinical research is tainted with manipulation and the historical mistreatment of minorities in clinical research.[237] The use of slaves for experiments, the Tuskegee Study, and unethical experimentation on minority prisoners, among other incidents, all contributed to minority fear of clinical research.[238] These fears still run deep.[239] Through the years, laws, regulations, and guidelines have been promulgated to avoid mistreatment of participants in clinical research.[240]

The development of informed consent has also played an important role in protecting subjects in clinical research.[241] The Nuremberg Code and the Declaration of Helsinki are just two examples of the international community's recognition of the importance of protecting human research subjects.[242] In the United States, the National Research Act was passed to protect research subjects, leading to the creation of the Belmont Report.[243] Guidelines have also been created to encourage minority inclusion in clinical treatment, in an effort to ameliorate past injustices.[244] The NIHRA was the beginning of a new line of thought, which actively considered minority participation in clinical research as a necessity.[245] This Act requires minorities to be included in clinical

companies "to make the effort to include diverse subject populations in trials of new therapies" by having the FDA offer market exclusivity or having journals require information on racial and ethnic subpopulations before being published. *Id.*

236. *See* NIH GUIDELINES, *supra* note 154, at 20.

237. *See id.* at 12; WASHINGTON, *supra* note 65, at 180; *supra* Part I.B.

238. *Supra* Part I.B.

239. *See id.*

240. *See supra* Part I.C.

241. Molly McGregor, *Uninformed Consent: The United Nations' Failure To Appropriately Police Clinical Trials in Developing Nations*, 31 SUFFOLK TRANSNAT'L L. REV. 103, 106–07 (2007).

242. *See* Office of Human Subjects Research, *supra* note 100; Office of Human Subjects Research, *supra* note 107.

243. *See* PROT. OF HUMAN SUBJECTS, *supra* note 98.

244. *See supra* Part III.

245. National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 289a-2 (2006).

research unless one of the exceptions is satisfied.[246] The NIHRA is a good beginning, but its exceptions too easily allow the exclusion of minorities, as well as ignoring cultural factors.[247]

It is important to include not only minorities, but also different cultures, in clinical research. Unfortunately, legislation and guidelines currently in place do not cover the entire landscape of clinical research.[248] Cultural differences in approaches to medicine are often overlooked, ignoring an important factor in medicine. Cultural variety has a significant impact on approaches to and views of medicine.[249]

Passage of appropriate comprehensive legislation can address the lack of consideration of cultural differences in clinical research participants.[250] Having this additional factor in the national dialogue will also provide a way for clinical research in the United States to evolve as the diversity of cultures and minority populations in the United States continues to increase. Congressional support will also help ensure fairness and proper inclusion in clinical research studies.[251]

Cultural specificity in clinical research is beneficial to researchers and subjects. By understanding and considering the participants' viewpoints, researchers make participants feel more comfortable, communicate with participants more easily, and obtain more accurate results.[252] Until such legislation is passed, cultural factors will continue to be overlooked, excluding some cultures and culturally significant factors from clinical research.

246. *Id.*

247. *See id.*

248. *See supra* Part III.C.

249. *See supra* Part II.C.

250. *See* Ranganathan & Bhopal, *supra* note 41, at 334 (arguing that governmental funding priorities in clinical research must be altered to include minority groups' health concerns).

251. *See, e.g., id.* (stating that researchers have responded favorably to NIH policies promoting the inclusion of minorities).

252. *See supra* Part IV.