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Rebecca A. Finkenbinder

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Recommended Citation
New Recommendations on International Human Research: Can Minimum Standards Prevent the Exploitation of Vulnerable Human Subjects in Developing Countries?

Rebecca A. Finkenbinder*

I. Abstract

Developed countries conduct clinical trials on humans in developing countries, primarily as the result of seeking lower costs. Specifically, the United States conducted HIV trials in Africa to test a new treatment to prevent the spread of AIDS from a mother to her child during birth. While the treatment is certainly worthwhile, the research utilized compromising ethical standards instead of the requisite United States human research regulations. In April 2001, new regulations were proposed by the National Bioethics Advisory Committee (NBAC) to govern such inconsistencies. Unfortunately, these recommendations, conceded by the NBAC to be “minimum standards,” are not sufficient to prevent the continuous exploitation of vulnerable research participants.

II. The Call for Regulation

In recent years, the scope of human research has rapidly expanded into the international playing field. Market forces, such as a steady decrease in federal funds, have spurred pharmaceutical, biotechnology and medical device companies to be more efficient in their methodology of conducting research.1 The United States and other developed countries have started to look outside their boundaries toward new sources for research subjects — developing countries. Poverty stricken

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and unable to receive even minimal healthcare, individuals in developing countries are vulnerable and serve as easy targets for scientists seeking subjects of research studies.  

Research studies conducted in these developing countries are highly scrutinized, considering the widespread potential for exploitation and unethical behavior. There are currently numerous sources of guidelines to help regulate the ethical conduct of researchers. None have thus far served as the necessary binding authority to ensure the protection of human subjects. A recent administrative study resulted in the proposal of "minimum standards" intended to promote human rights and increase the welfare of every research participant. The question remains whether these elementary guidelines will protect and stop the exploitation of vulnerable human beings.

This comment examines the new "minimum standards" as they are applied to studies conducted in developing countries, with particular attention to a recent research study conducted in Africa. In Section III, a detailed description of the drug trials is given in addition to an analysis of the resulting ethical controversy. Section IV provides a review of the most relevant national and international human research guidelines. Section V discusses the new recommendations recently proposed to address unethical behavior that has now become prevalent when developed countries conduct research in developing countries. Moreover, this section will analyze whether the new standards would have protected the human subjects in the African drug trials. Finally, Section VI provides a brief summary of the comment.

III. The AIDS Epidemic

Since its dawning, the human immunodeficiency virus (HIV) pandemic has adversely affected approximately five million children, ninety percent of whom live in Africa. Of those with the disease, more than one million children contracted HIV through mother-to-child transmission (MTCT). MTCT of HIV can occur during pregnancy,

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3. EXECUTIVE SUMMARY, supra note 1, at xiv.
delivery, or breastfeeding.\textsuperscript{6} Women in sub-Saharan Africa have the highest rates of MTCT, due to the fact that many women breastfeed for approximately two years.\textsuperscript{7} Despite the apparent link between breastfeeding and the transmission of HIV, infants born to HIV-infected mothers continue to acquire this fatal disease because breastfeeding is more economical in developing countries.\textsuperscript{8}

A. AZT Trials in United States

An overwhelming source of HIV infection in children, MTCT has caught the attention of the United States federal government, sparking a plethora of federally funded research studies worldwide. In 1991, the National Institute of Health (NIH) conducted an HIV clinical trial, in the United States, entitled ACTG-076 (hereinafter “the 076 regime.”) The women in the study agreed to receive a drug, AZT, or a placebo throughout their pregnancies and delivery. Neither the subjects nor the doctors knew which “treatment” was given.\textsuperscript{9}

In early 1994, results of the trial concluded that it is possible to reduce the risk of MTCT of HIV by as much as two-thirds by giving HIV-infected women AZT during pregnancy, labor, and delivery, and subsequently administering AZT to the newborn infants.\textsuperscript{10} As a result, the study came to a halt in fifty-nine medical centers; officials ordered AZT be administered in place of the placebo to the women participating in the study.\textsuperscript{11} Subsequently, the 076 regime became the “standard of care” in the United States.\textsuperscript{12} As a result of this new drug, HIV infections in children living in the United States dramatically decreased.\textsuperscript{13}

\begin{itemize}
\item \textsuperscript{6} Breastfeeding Transmission, supra note 4.
\item \textsuperscript{7} Id.
\item \textsuperscript{8} New Data on the Prevention of Mother-to-Child Transmission of HIV and their Policy Implications: Conclusions and Recommendations (Jan. 15, 2001), at http://www.unaids.org/publications/documents /mtct/index.html (last visited Oct. 16, 2002). Twenty-five to 35% of HIV-positive women’s babies will become infected in developing countries, while the probability of transmission in industrialized countries is only 15% to 25%. Mother-to-Child Transmission, supra note 4.
\item \textsuperscript{10} Perinatal HIV Prevention, supra note 5. See also CDC Studies of AZT to Prevent Mother-to-Child HIV Transmission in Developing Countries: Questions and Answers (June 1997), at http://www.hivatis.org/devlques.html (last visited Oct. 16, 2002) [hereinafter Questions and Answers].
\item \textsuperscript{11} Altman, supra note 9.
\item \textsuperscript{12} Questions and Answers, supra note 10.
\item \textsuperscript{13} Id. Three years after the trials, the number United States children born with HIV had decreased to approximately 500 per year, as compared with 1,800 per year in the early 1990s. Susan Okie, HIV Transmission's Two Worlds; Mother-to-Baby Rates Down Here, Not in Poor Countries, THE WASH. POST, Sep. 16, 1997, at Z07 [hereinafter Baby
B. Implementing AZT Throughout the World

A conference was held shortly after the trial in the United States was complete; researchers and health practitioners worldwide convened to discuss the implications of the results for developing countries. The panel suggested the 076 regime be used in industrialized nations, but agreed that it would need to be altered before implemented in developing countries. In its recommendations, the international panel focused its research efforts on a simpler, less costly drug regime, due to many obstacles precluding the implementation of the 076 regime in the newly developed world.

1. Barriers to Implementation

Among the barriers that influenced the panel's decision to preclude the implementation of the 076 regime in underdeveloped countries such as Africa were the cost and feasibility of the drug treatment. Drug costs alone for the 076 regime were estimated around $800, which was eighty times the annual budget per person in many developing nations. The panel also deemed the 076 regime unfeasible due to its requirements that women be treated early in their pregnancy and receive intravenous administration of AZT. In developing nations, women infrequently seek and receive prenatal care, and intravenous treatment is not readily available.

Due to these obstacles to implementation and the fact that no treatment is available in most developing countries, the panel recommended that placebo-controlled trials be designed to provide faster, yet valid assessments of drug treatments to HIV-infected women. Despite the fact that there is a standard of care in the United Rates]. The 076 regime is estimated to save the life of one of every seven children born to HIV-infected women. Peter Lurie & Sidney M. Wolfe, Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries, 337 N. ENGL. J. MED. 853, 853 (1997).

14. Perinatal HIV Prevention, supra note 5.
15. Id.
16. Id.
17. Costs to treat both the pregnant mother and the newborn range between $400 to $900. Baby Rates, supra note 13.
18. Perinatal HIV Prevention, supra note 5. Annual national health budgets in the developing world are generally less than $10 per person. Questions and Answers, supra note 10.
19. Perinatal HIV Prevention, supra note 5.
20. Most pregnant women in developing countries do not seek prenatal care until they begin labor. Mother-to-Child Transmission, supra note 4.
21. Perinatal HIV Prevention, supra note 5.
22. Id.
States, a placebo-controlled design was developed, with the rationale that alternative regimes should be compared to the standard of care in most developing countries, that is, no treatment.\textsuperscript{23}

2. Modified AZT Trials in Africa

As a result of these recommendations, the NIH and the Centers for Disease Control and Prevention (CDC) financed placebo-controlled studies conducted in developing countries, with an emphasis in Africa.\textsuperscript{24} In particular, studies in the Cote d’Ivoire (hereinafter “Ivory Coast”) were conducted that consisted of a shorter course AZT regimen given to HIV-infected women late in their pregnancies.\textsuperscript{25} Specifically, the women only received oral AZT in the last four weeks of pregnancy and during labor, as compared to the trial in the United States where the women received AZT orally for sixteen to twenty-four weeks and intravenously during childbirth.\textsuperscript{26} Researchers, in an attempt to find an affordable and feasible therapy option in the developing world, believed this newly designed regimen would prove to be effective, safer and could be realistically implemented.\textsuperscript{27}

Critics argue that the shorter dose regimen research is unethical as administered in developing countries because the research makes use of a placebo in the study, while there is already a clinically proven treatment that is now the standard of care in the United States. The CDC, in fact, has conceded that scientific studies are usually conducted by comparing a new treatment with the standard treatment.\textsuperscript{28} As a result, opponents of the studies declare all perinatal transmission studies that use placebos unethical; any regimen shorter and more economical should be compared to the longer course of AZT.\textsuperscript{29} In particular, critics argue that approximately 1,000 babies of women in these studies could have been spared becoming infected with HIV through MTCT if their mothers had been assigned the standard treatment and not a placebo.\textsuperscript{30}

Defenders of the placebo-controlled studies argue that the standard of care in the host country is to be considered the standard, which, in this

\textsuperscript{23} Id.
\textsuperscript{24} See Questions and Answers, supra note 10.
\textsuperscript{25} Id.
\textsuperscript{26} Id. In addition, while the United States’ trial gave the newborns AZT for six weeks after their births, the much shorter regimen in the Ivory Coast gave no infant dose because it was simpler and less expensive. Perinatal HIV Prevention, supra note 5.
\textsuperscript{27} Perinatal HIV Prevention, supra note 5.
\textsuperscript{28} See Questions and Answers, supra note 10.
\textsuperscript{30} Baby Rates, supra note 13.
case, is no treatment at all. These health officials agree to the administration of a smaller dose because it would be a faster and more economical method of treatment in developing countries that would not normally be available to those HIV-infected women. The CDC is adamant that a study comparing a shorter dose to the clinically proven longer dose "would not indicate whether the short AZT regimen was better than the currently available intervention[]."

At the same time that the shorter regimen was administered to Ivory Coast women, similar trials were conducted in Thailand. On February 18, 1998, a nearly completed study in Thailand revealed that a short and relatively inexpensive regimen of AZT is almost as effective as the longer dose administered in 1994 to the women in the United States. Consequently, health officials recommended all other studies, including those in the Ivory Coast, to stop the use of placebos. Critics of the placebo-controlled studies believe that the decision to cease the use of placebos is dispositive that the practice is unethical.

Unfortunately, the effectiveness of AZT in substantially decreasing the transmission of HIV to newborns has only been realized in non-breastfed infants. In populations like the Ivory Coast, where breastfeeding is not only the norm but also the only economical method of feeding, these studies are severely limited in their effectiveness and application in developing countries.

If the shorter dose of AZT is not as effective in breastfeeding women, why do they remain the targets of federal funding for drug


33. See Questions and Answers, supra note 10.

34. In addition to the Ivory Coast, AZT studies were conducted in Thailand, Uganda and Ethiopia. Baby Rates, supra note 13.


36. Id.


39. Many obstacles to replacement feedings that HIV-infected mothers in developing countries face include stigma, affordability, risk to the infant of other infections and malnutrition. Id.

40. "Results from a number of studies in breastfeeding populations indicate that a
research? Perhaps industrialized nations are exploiting those in other countries by taking advantage of and capitalizing on their unfortunate situations; in this case, the AIDS epidemic.

C. Controversy Erupts Regarding Ethical Issues

The consensus remained that the full 076 regimen could not be implemented as the standard of care in developing nations. Both sides of the controversy agreed that perinatal HIV transmission is a grave problem meriting concerted international attentions; that the ACTG 076 trial was a major breakthrough in perinatal HIV prevention; that there is a role for research on this topic in developing countries; that identifying less expensive, similarly effective interventions would be of enormous benefit, given the limited resources for medical care in most developing countries; and that randomized studies can help identify such interventions.

One point of disagreement in this ethical controversy, however, is what comparison group should be used when there is a known effective intervention, but a more economical intervention is being tested? Another important ethical consideration is whether there are known mechanisms for implementing the shorter dose once the studies are complete. Women in developing countries cannot afford even the shorter dose; therefore, the less effective, low-cost interventions improve upon nothing at all.

International AIDS officials rely on donations and price breaks by the manufacturer of AZT, so that the two to three million women a year who need treatment can have access to the drug. However, the NIH, the CDC and the host countries have not developed a plan as to how to

short course of [AZT] can still reduce the transmission of HIV from the mother to the baby, though not as well as when mothers do not breastfeed." Mother-to-Child Transmission, supra note 4.

41. Questions and Answers, supra note 10. The consensus is among the World Health Organization (WHO), Joint United Nations Programme on HIV/AIDS (UNAIDS), and those countries where the trials are being conducted. Id.

42. Lurie & Wolfe, supra note 13, at 854.

43. See id.

44. Susser, supra note 35. "The particular and pressing issue is how to make the new intervention, or other alternatives to the standard regimen, affordable in the poorest nations." Id. One critic of the placebo-controlled studies goes as far to say that the research conducted was "inexcusable" and "sloppy" because "they have wasted a large number of lives and a huge amount of money" doing it. Sheryl Gay Stolberg, Placebo Use is Suspended in Overseas AIDS Trials, N.Y. TIMES, Feb. 19, 1998, at A6.

45. Glaxo-Wellcome is the manufacturer of AZT.

46. See Brown, supra note 29.
make the interventions available, and have given no realistic assurances that a plan will emerge. Therefore, the mere assertions by health advocates that the interventions are feasible in developing nations is simply "just paying lip service" and is not "good enough" to help needy women and children. In fact, a South Africa pediatrician wonders if the health officials who financed the trials will pay for the women in her country to receive the drug after the study is completed and claims "they should put their money where their mouth is."

The NIH and the CDC maintain that the Ivory Coast research is ethical, primarily because there is no current treatment available. In addition, the CDC believes that the studies are consistent with both the United States and international human research ethical standards. Furthermore, the CDC feels compelled to conduct such studies, as it may be unethical not to undertake them, considering its ability to address such a critical international issue.

Another argument in favor of the trials is that the host countries, in fact, approached the United States to help find a treatment that is better than what they have now. Yet government records show that African collaborators of the studies did not feel comfortable using a placebo and a Harvard doctor in the Thailand trials refused to administer any dummy medications. In fact, none of the Thai women in the Thai government’s study received a placebo. Nevertheless, the trials conducted in the Ivory Coast continued to use a placebo when a known dosage of AZT was determined effective and could eliminate the deaths of many children.

48. Id.
50. Questions and Answers, supra note 10. In fact, the CDC stated "the idea that there is AZT somewhere in the world doesn't have a real bearing on the lives of these children and their mothers." Susan Okie, Researchers Assailed for AIDS Studies on Pregnant Women in Third World, THE WASH. POST, Sep. 18, 1997, at A13 [hereinafter AIDS Studies].
51. See Questions and Answers, supra note 10.
52. See id.
53. AIDS Studies, supra note 50. See also David D. Ho, It's AIDS, Not Tuskegee; Inflammatory Comparisons Won't Save Lives in Africa, TIME, Sep. 29, 1997, at 83. ("African researchers sought sponsorship from U.S. health agencies.")
54. Ethics Outcry, supra note 49.
55. Id.
56. See infra text accompanying note 152.
IV. Human Research Regulations

The AZT trials were certainly not the first research studies conducted on human beings. Human research is commonplace in the medical industry and the need for regulation in this growing area arose long before HIV and AIDS. Unfortunately, the conduct that spurred the first guidelines is analogous to the AZT trials — both resulted in the death of many innocent lives.

A. International Regulations

1. The Nuremberg Code

The atrocities committed by the Nazis during the Second World War resulted in the creation of an ethical framework that has served as a guide for all current and future regulation of human experimentation. An inhuman combination of Social Darwinism, Nazi ideology and "racial hygiene" fostered an atmosphere where innocent victims were exploited and subject to hideous crimes. Following the war, twenty-three Nazi physicians and scientists were charged with war crimes involving the performance of medical experiments on nonconsenting prisoners held primarily at concentration camps.

The Doctors' Trial (the "Trial") was held in postwar Nuremberg Germany in December 1946 and concluded eight months later. The Trial provided the opportunity to analyze the legal and ethical implications of human experimentation. As a result, The Nuremberg Code (the "Code"), was drafted by four American judges, not as a code

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58. The court's judgment described the hideousness of the crimes: "[A]ll of these experiments involving brutalities, tortures, disabling injury, and death were performed in complete disregard of international conventions, the laws and customs of war, the general principles of criminal law as derived from the criminal laws of all civilized nations, and Control Council, Law No. 10. Manifestly human experiments under such conditions are contrary to 'the principles of the law of nations as they result from the usages established among civilized people, from the laws of humanity, and from the dictates of public conscience.'" Judgment and Aftermath, in THE NAZI DOCTORS, supra note 57, at 94, 104 [hereinafter Judgment].


60. Fifteen of the twenty-three were convicted, seven were hung to death, five received life imprisonment, and four were sentenced to ten to twenty years imprisonment. Seven were found not guilty. Epilogue, supra note 59, at 105.

61. President Truman appointed the four judges of the United States Military Tribunal No. 1. See id. at 113. In addition, the Doctors' Trial was conducted under the
of medical ethics, but formulated as part of the final legal judgment in the criminal case. The court agreed that "certain basic principles must be observed in order to satisfy moral, ethical and legal concepts." Consisting of ten principles, the Code serves as the hallmark for all future regulations on the ethics of human experimentation with the underlying premise of protecting a research subject's rights and well-being. Though the Code identified its essential principle, voluntary consent of a human subject, over fifty years ago, it has no doubt influenced the world and its subsequent promulgation of ethical codes. Notably, the informed voluntary consent principle was listed first. Voluntary informed consent is its crucial centerpiece and, subsequently, the protection of subjects remains a paramount concern in any human experiment.

Unfortunately, the Code is not a perfect document and violations surfaced shortly after its formulation. Hence, the need for a more comprehensive set of ethical regulations, promulgated by physicians, and not judges, emerged. The Code, however, would serve as a guide to a new set of principles.


63. Judgment, supra note 58, at 102.


65. MICHAEL A. GRODIN, Historical Origins of the Nuremberg Code, in THE NAZI DOCTORS, supra note 57, at 121, 122 [hereinafter Historical Origins].


67. See Historical Origins, supra note 65, at 122.

68. See International Overview, supra note 66, at 168. The Code's "imperfections do not, and should not, minimize its importance. For although the field of international research ethics has evolved greatly over the past 40 years, its origins can always be traced back to the 10 principles first enumerated at the trial of the Nazi physicians." Id.

69. See id. at 157. One example of the United States violating the Code is its conduct during the Vietnam War. United States soldiers breathed Agent Orange and were subsequently harmed by this new chemical. ROBERT F. DRINAN, The Nuremberg Principles in International Law, in THE NAZI DOCTORS, supra note 57, at 174, 179. See also Ethics versus Expediency, supra note 61, at 219. ("The promise of the Nuremberg Code has not been fulfilled in the United States.") In fact, the Code has never been used in an United States court to award damages in a criminal case since its formation. While the Code may serve as authority on criminal and civil standards of conduct, only one Supreme Court case, United States v. Stanley, 483 U.S. 669, (1987), mentions it—in the dissent. Ethics versus Expediency, at 201, 212.

70. International Overview, supra note 66, at 157.
2. Declaration of Helsinki

The World Medical Association (WMA) began studying the dilemma of the formation of a new ethical code and, in 1964, promulgated the Declaration of Helsinki (Helsinki I). Helsinki I identified five basic principles to be followed when humans serve as subjects to experimentation. A notable difference between Helsinki I and the Code is the location of the informed consent requirement. Unlike the Code, Helsinki I does not include as one of its five basic principles the critical principle of voluntary, informed consent.

While other differences are apparent, another significant difference between the Code and Helsinki I is its clear differentiation between "clinical research combined with professional care" and "nontherapeutic clinical research." It is within this distinction that Helsinki I placed the profound informed consent principle and expanded the original consent requirement to include a provision for those that are incapable of giving consent and suggested that consent be obtained in writing.

Helsinki I was revised in 1975 (Helsinki II), 1983 (Helsinki III) and 1989 (Helsinki IV); Helsinki II is recognized as the fundamental comprehensive set of principles for research involving human subjects. Its final revision features twelve basic principles and has been adopted by international texts and national legislation.

Helsinki II changed the terminology of Helsinki I to "Clinical Research" and "Non-Clinical Biomedical Research." In addition, it emphasized the informed consent requirement by placing it among the twelve basic principles and expanding it to include three principles. Furthermore, Helsinki II, for the first time, created a deterrent (though minimal) to the exploitation of human subjects; those experiments not in compliance with the principles will not be accepted for publication.

Moreover, in terms of the current issue, Helsinki II requires research on human subjects to conform to "generally accepted scientific principles." Unfortunately, it does not specify whose scientific principles are to be considered acceptable — the principles of the

71. The Committee on Medical Ethics was selected to "grapple" with the issue. Id.
72. While the Code served as a guide, it was never mentioned in Helsinki I or any successive drafts of the Declaration of Helsinki.
73. See generally, DECLARATION OF HELSINKI: RECOMMENDATIONS GUIDING MEDICAL DOCTORS IN CLINICAL RESEARCH, reprinted in THE NAZI DOCTORS, supra note 57, at 331 [hereinafter DECLARATION OF HELSINKI I-IV].
74. International Overview, supra note 66, at 158.
75. Id. at 159.
76. Id.
77. DECLARATION OF HELSINKI I-IV, supra note 73, HELSINKI II, Principle II, III.
78. Id., Principle I.9-11.
80. Id., Principle I.1.
sponsoring or the host nation. In addition, Helsinki II requires every patient to be assured of, and any new treatment to be weighed against, the "best current diagnostic and therapeutic methods." This provision of the international document also does not provide further guidance regarding whether the "best current diagnostic and therapeutic methods" are to be defined in terms of the sponsoring or the host country.

While the Code and the Declaration of Helsinki provide the basis for universality of ethical standards in human experimentation, neither holds legally binding authority. Therefore, binding ethical standards in the form of national or international regulations were still needed.


In 1982, the Council for International Organizations of Medical Sciences (CIOMS), with the assistance of the World Health Organization (WHO), issued one of the most significant developments in the international realm of medical research ethics: "Proposed International Guidelines for Biomedical Research Involving Human Subjects" (the "Guidelines"). The Guidelines are based on Helsinki II and serve as a guide to countries promulgating their own regulations regarding ethical conduct in research involving human subjects.

The Guidelines provide the first source of standards for international research conducted by developed countries in developing countries. In particular, it requires research to be completed by subjects in developed countries, unless certain circumstances necessitate elsewhere. Intended to protect human subjects' rights, the Guidelines identify vulnerable groups who may be incapable of protecting their own

81. Id., Principle II.2, II.3.
82. International Overview, supra note 66, at 160. One commentator noted "the various declarations and codes defining ethical aspects of research on human subjects [are] really no more than pious hopes that doctors [will] behave ethically." Id. (quoting ALFRED GELLHORN, Medical Ethics in the Modern World, in MEDICAL EXPERIMENTATION AND THE PROTECTION OF HUMAN RIGHTS, at 9 (Norman Howard-Jones & Zbigniew Bankowski, eds., Geneva: Council for International Organizations of Medical Sciences and Sandoz Institute for Health and Socio-Economic Studies, 1979)).
83. See International Overview, supra note 66, at 160.
84. Id. The authors note that the word "proposed" does not mean that the guidelines have not been promulgated, rather the guidelines are proposed to countries as national standards of ethical conduct. Id. at 160-61.
85. See id. at 162. The guidelines are meant to provide a "framework upon which countries that have not yet formalized their regulatory requirements for the ethical review of research protocols may build." Id.
86. PROPOSED INTERNATIONAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS, reprinted in ETHICS AND RESEARCH ON HUMAN BEINGS: INTERNATIONAL GUIDELINES (Z. Bankowski & R.J. Levine eds., 1993), Guideline 8 [hereinafter PROPOSED INTERNATIONAL GUIDELINES].
interests due to a host of impediments. The Guidelines identify duties that an investigator must follow before obtaining informed consent. Specifically, an investigator has the obligation to give potential subjects pertinent information to aid in their decision to participate in the research and to exclude all possibilities of coercion or undue influence.

Concerned that investigators in developed countries may serve self-interests rather than the interests of the human subjects in the developing countries, the Guidelines mandate the ethical review of all experiments by both the sponsoring and the host country. Based on these new ethical guidelines, the emphasis is no longer on the informed consent of the subject, but rather on the ethical review of the experimental procedure itself. Hence, the Guidelines diverge from the two previous international standards, yet still capture the essence of the underlying principle — protection of a research subject's rights and well-being.

The most significant distinction from the other international codes, as viewed in terms of this comment, is the Guidelines' implication that the ethical standards applied by the ethical review committee be "no less exacting than they would be in the case of research carried out in [the sponsoring] country." Therefore, while the Guidelines do not provide the legal authority on ethical standards that they were hoped to have provided, they offer critics of the trials conducted in the Ivory Coast an origin for their argument that regulations of the United States should govern the research it conducts in developing nations.

B. United States Regulations

1. The Belmont Report

In 1979, the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the "Commission") promulgated the Belmont Report: a statement of basic ethical principles and guidelines signed into law to assist scientists, subjects, reviewers, and interested citizens in resolving ethical issues.

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87. PROPOSED INTERNATIONAL GUIDELINES, supra note 86, Guideline 10.
88. Id., Guideline 3.
89. Id., Guideline 15.
90. See International Overview, supra note 66, at 163. "By mandating ethical review, the Guidelines provide for exceptions to the absolute requirement of informed consent in instances where consent may not be obtainable, yet experimentation on human subjects may still be ethically and morally justified." Id.
91. Id. at 165. "Even though the emphasis has shifted from informed consent to ethical review, the underlying principles, established to protect the rights and welfare of the research subject, remain basically the same." Id. at 164.
92. PROPOSED INTERNATIONAL GUIDELINES, supra note 86, Guideline 15.
stemming from human experimentation.93

The Belmont Report identifies three basic ethical principles: autonomy, beneficence, and justice.94 Autonomy requires respect for persons and protection for those with a diminished capability of self-determination.95 Respect for those participating as human subjects demands that they are adequately informed before they voluntarily consent to the research.96

Beneficence is an extension of the Hippocratic maxim "do no harm."97 The Commission defined beneficence as an obligation to (1) do no harm and (2) maximize possible benefits while minimizing possible harms.98 Investigators are obligated to maximize the benefits of the research and reduce the risk to subjects that may arise during the experiment.99

Finally, justice requires that everyone be treated equally. In the human research realm, justice demands that the selection of subjects be random, rather than systematically selected on the basis of their manipulability or compromised situation.100 In addition, justice requires that the advantages of the studies benefit all that participate, not just those that can afford them.101

2. Department of Health and Human Services and the Food and Drug Administration.

In 1990, both the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) passed federal legislation, which provided additional guidance for the protection of human research subjects.102 These regulations delineate a heightened importance on obtaining informed consent from every participant before research is conducted.

Essentially, the two pieces of legislation are identical; both identify eight basic requirements for informed consent, along with additional elements that may be appropriate in certain situations such as when research is conducted on embryos or fetuses.103 The general requirements identify the specific information that must be given to the

94. Id. at 23193-94.
95. Id. at 23193.
96. Id. at 23194.
97. Id.
98. Id.
99. THE BELMONT REPORT, supra note 93, at 23194.
100. Id.
101. See id.
103. Id.
potential subjects prior to the start of the research including an explanation of the purpose(s) of the research, a description of all foreseeable risks and a disclosure of any benefits to the participants.\textsuperscript{104}

In addition, the regulations require the research subject(s) to be given the opportunity to decline participation prior to the investigator obtaining the subject’s consent.\textsuperscript{105} Of utmost importance, the investigator must ensure that the participant is not subject to coercion or undue influence and must provide all pertinent information in a language that is understandable to the subject.\textsuperscript{106}

V. National Bioethics Advisory Commission 2001 Recommendations

Due to the increasing number of developed countries conducting research on subjects in developing countries, with specific attention on the AZT trials in the Ivory Coast, questions regarding the ethics of these studies emerged.\textsuperscript{107} In particular, there was a growing concern that the research was, or had the potential for, exploiting both the host country and those who participated in the research studies.\textsuperscript{108} Once again, readily identifiable research standards were desired in order to ensure the safety of those involved in human experimentation.\textsuperscript{109}

On October 3, 1995, President Clinton signed an executive order\textsuperscript{110} creating the National Bioethics Advisory Commission (NBAC).\textsuperscript{111} The NBAC’s essential functions included providing guidance to the National Science and Technology Council and other government entities on matters regarding government regulations addressing “bioethical issues arising from research on human biology and behavior.”\textsuperscript{112} In addition, the NBAC was required to identify broad principles that would govern the ethical conduct of human research.\textsuperscript{113} More specifically, the NBAC

\textsuperscript{104} Id.
\textsuperscript{105} Id.
\textsuperscript{106} Id.
\textsuperscript{107} See EXECUTIVE SUMMARY, supra note 1, at i.
\textsuperscript{108} Id.
\textsuperscript{109} Many issues were contributing to the need for a comprehensive study on ethical standards of human research. Among other issues, scientists in developing countries are achieving equitable status as researchers and there is a growing concern that United States regulations were simply “bundled” and “exported” to other countries, forcing the host country to interpret them. 1 NBAC ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH: CLINICAL TRIALS IN DEVELOPING COUNTRIES: REPORT AND RECOMMENDATIONS, at 3 (2001) [hereinafter REPORT AND RECOMMENDATIONS] available at http://www.georgetown.edu/research/nrcbi/nbac/pubs.html.
\textsuperscript{110} Exec. Order No. 12975.
\textsuperscript{111} The NBAC consisted of Harold T. Shapiro, Ph.D., serving as the NBAC chair, and seventeen other members. In addition, an extensive research staff and other consultants contributed to this expansive study of bioethics.
\textsuperscript{112} EXECUTIVE SUMMARY, supra note 1, inside front cover.
\textsuperscript{113} Id.
was to investigate whether the existing rules and regulations' governing the United States' expanding realm of human research, remain the appropriate standards when such research is conducted outside the United States.\textsuperscript{114}

In April 2001, the NBAC published its final report,\textsuperscript{115} proposing twenty-eight recommendations that addressed the ethical issues that arise when research, which is subject to United States regulation, is sponsored or conducted in developing countries. These recommendations stress the need for sponsoring countries to assist the host countries in becoming capable of self-regulating human research conducted within its boundaries.\textsuperscript{116} However, until this need is met, the NBAC's recommendations will serve as a basis for how the "United States should proceed in settings in which systems for protecting human participants equivalent to those of the United States have not yet been established."\textsuperscript{117}

Essentially, the NBAC's recommendations serve as the substantive ethical requirements for protecting those involved in human experimentation. Of primary concern is the NBAC's perspective regarding its recommendations: "Although the ethical standards that this report is recommending for conducting research in other countries are minimum standards, host countries are encouraged to adopt human research participant protections that go beyond those that are currently provided under the United States system."\textsuperscript{118} This comment will only focus on those "minimum" recommendations that specifically address three paramount ethical issues: informed consent, placebo versus best available treatment and availability of treatment after the research trials.

The NBAC stressed that all international research conducted on humans should conform, at a minimum, to the ethical principles delineated in the Belmont Report.\textsuperscript{119} Therefore, its first recommendation states:

\textit{Recommendation 1.1:} The U.S. government should not sponsor or conduct clinical trials that do not, at a minimum, provide the following ethical protections:

a) prior review of research by an ethics review committee(s);

\textsuperscript{114} See id. at i.
\textsuperscript{115} This report represents the fifth NBAC report, submitted to President Clinton. It is the culmination of eighteen months of study, focusing on both domestic and international standards of bioethics. Letter from Harold T. Shapiro, Chair, National Bioethics Advisory Commission, to President Clinton (April 18, 2001), reprinted in \textsc{REPORT AND RECOMMENDATIONS, supra} note 109, at 1.
\textsuperscript{116} \textsc{EXECUTIVE SUMMARY, supra} note 1, at ii.
\textsuperscript{117} \textit{Id.}
\textsuperscript{118} \textsc{REPORT AND RECOMMENDATIONS, supra} note 109, at 6.
\textsuperscript{119} See id. at 5.
b) minimization of risk to research participants;


c) risks of harm that are reasonable in relation to potential benefits;

d) adequate care of and compensation to participants for injuries directly sustained during research;

e) individual informed consent from all competent adult participants in research;

f) equal regard for all participants; and

g) equitable distribution of the burdens and benefits of research.120

While this preliminary recommendation serves as an overview, subsequent recommendations delineate how to specifically meet the NBAC's "minimum standards." For example, obtaining voluntary informed consent from every research subject has proven difficult, especially in developing countries, where a plethora of communication barriers exist. Therefore, the NBAC provided further guidance on overcoming obstacles when obtaining informed consent.

A. Informed Consent

Obtaining voluntary informed consent has been a fundamental principle of research ethics, as evident in the Declaration of Helsinki, the Belmont Report and both the DHHS and the FDA requirements.121 Its necessity stems from the simple fact that "the use of human beings as a means to the ends of others without their knowledge and freely granted permission constitutes exploitation and is therefore unethical."122

For the purposes of its report, the NBAC adopted as the definition of informed consent: "the process by which an individual voluntarily expresses his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the decision to participate."123 The NBAC, elevating substance over form, stressed the process of obtaining the consent rather than the document

120. Id., Recommendation 1.1, at 6.

121. The requirement of informed consent is "reflected in all published national and international codes, regulations, and guidelines pertaining to research ethics, including those in many developing countries." Report and Recommendations, supra note 109, at 35.

122. See id. at 36.

123. Id. at 37. The NBAC adopted this definition from the International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice, GCP Guideline 1.28 (ICH 1996). Report and Recommendations, supra note 109, at 37. Utilizing this definition, the NBAC recommended: "Research should not deviate from the substantive ethical standard of voluntary informed consent. Researchers should not propose, sponsors should not support, and ethics review committees should not approve research that deviates from this substantive ethical standard." Id., Recommendation 3.1, at 38.
that contains the written consent of the participant. Finally, the NBAC made further recommendations to ensure the consent process is ethical.

1. Cultural Issues Related to Presenting Information to Participants

The NBAC considered four types of disclosure fundamental to achieving voluntary informed consent: disclosure of diagnosis and risk, disclosure of the use of placebos and randomization, disclosure of alternative treatments and disclosure about possible post-trial benefits. These four disclosures are important because cultural differences arise within each and in order to ensure every subject completely understands the research to be conducted, investigators must first be aware of the difficulties they may face in other countries. In its report, the NBAC stressed that these cultural differences shall not be overlooked when obtaining consent from research subjects.

Another obvious cultural barrier is language. Participants may not fully understand the technical and scientific jargon underlying the studies. Countries with low literacy rates, including the Ivory Coast, may not even understand a written consent form. Furthermore, in some countries, certain individuals are unable to decide for themselves whether they may participate in the protocol.

To address these additional cultural barriers, the NBAC proposed the following recommendations:

Recommendation 3.4: Researchers should develop procedures to

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124. *Id.* at 37.
125. The NBAC identified the ideal consent process: the sponsoring team provides information to the subject and ensures that the subject voluntarily agrees to the research study only after the team makes a determination that the subject understands the information provided to him or her. REPORT AND RECOMMENDATIONS, *supra* note 109, at 37.
126. “Researchers should develop culturally appropriate ways to disclose information that is necessary for adherence to the substantive ethical standard of informed consent, with particular attention to disclosures relating to diagnosis and risk, research design, and possible post-trial benefits. Researchers should describe in their protocols and justify to the ethics review committee(s) the procedures they plan to use for disclosing such information to participants.” *Id., Recommendation 3.2*, at 40.
127. For example, in some countries, it is customary for physicians to routinely withhold certain information from their patients, whether in a clinical or research setting. See REPORT AND RECOMMENDATIONS, *supra* note 109, at 38-39.
128. *Id.* at 39-40.
129. *Id.* at 40.
130. *See id.* at 41.
131. Instead, a community leader or a woman’s spouse or father must first give permission for the individual to become a research subject. Moreover, researchers may have to seek a community leader’s consent before even approaching potential participants. *Id.* at 42-44.
ensure that potential participants do, in fact, understand the information provided in the consent process and should describe those procedures in their research protocols.

**Recommendation 3.5:** Researchers should consult with community representatives to develop innovative and effective means to communicate all necessary information in a manner that is understandable to potential participants. When community representatives will not be involved, the protocol presented to the ethics review committee should justify why such involvement is not possible or relevant.\(^{132}\)

Despite the apparent "ethical centrality" of informed consent in research regulations, problems exist not only because of cultural differences resulting in ineffective communication, but also because the standard is, in fact, *not* universally embraced.\(^{133}\) Nonetheless, the NBAC felt confident that United States investigators, even faced with cultural diversity, would be able to obtain voluntary informed consent.\(^{134}\) In fact, while the NBAC has repeatedly admitted the difficulties in implementing sound procedures to overcome cultural barriers,\(^{135}\) it still maintains that voluntary informed consent can be obtained.\(^{136}\)

Considering the various cultural barriers, it is simply not feasible that every participant will fully understand research procedures in order to voluntarily consent to the study. In fact, it is not too harsh a statement that there should be a presumption that consent *cannot* be adequately obtained when international research is conducted by a foreign nation in a developing country.\(^{137}\)

The NBAC recommended that "[r]esearchers should develop culturally appropriate ways to disclose information,"\(^{138}\) and gave substantive examples researchers can use to ensure adequate disclosure and understanding.\(^{139}\) While the NBAC identified the potential areas in which cultural differences will be most prevalent, it nonetheless still

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132. See Report and Recommendations, supra note 109, Recommendation 3.4, 3.5, at 42.

133. See id. at 35. One commentator states that it "is 'ethical imperialism' at its worst to assume that the informed consent requirement . . . is in itself such a universal ethical standard." Id. at 36.

134. See id. at 36.

135. "Although the Commission recognizes the challenges raised by these cultural differences . . . Despite the acknowledged difficulties of administering tests of understanding . . ." Id. at 40-42.

136. See id. at 50.

137. See Maternal-Fetal HIV Transmission, supra note 47.


139. See Report and Recommendations, supra note 109, at 41.
leaves the method of disclosure to the investigators themselves.

In fact, the NBAC claimed that if researchers are "willing to devote the time and effort to do so, [they] often are able to devise creative measures for overcoming the cultural barriers." Hence, discretion in the methodology and the amount of information given to research subjects remains with the investigators. As seen thus far, regulations that provide no clear-cut guidelines have resulted in exploitation or the potential exploitation of human beings in developing countries because researchers are not willing to make the time or effort to ensure clear communication with their subjects.

2. Issues Relating to Voluntary Participation in Research

The NBAC denoted that the fundamental principle of informed consent requires that consent be voluntary. However, ensuring that a subject remains free of coercion and undue influence is among the most difficult requirements. It is unlikely that a research subject would willingly participate in a research study if it was void of any benefits to the community or to him or herself. If participants are offered medical treatment, to which they would not normally have access, however, they may consent to the research to obtain the medicine. Thus, while the research subject's consent has been voluntarily obtained, it was only obtained because the subject wished to receive free medication. Hence, individuals, such as the pregnant women taking the AZT drug, may be unduly influenced to participate in research studies that provide even minimal treatment.

When asked if it believed that the AZT studies were ethical, the CDC not only stated that the studies were consistent with both the United States and international ethical standards but it also outlined the vast amount of information that was given to the participants.
Nevertheless, the participants in the studies were not adequately informed and merely consented because of the medicine they would receive.

One AZT participant reported that she did “not quite grasp — even after repeated questioning” what drug she was taking and for what purpose. Moreover, she, along with most of the other participants, admitted that she consented to the research because it provided her and her baby free medical care that she otherwise would have been unable to receive. Most participants agreed that the prospect of help during and after their pregnancy “made taking part in the experiment all but irresistible.” Some women only received a five minute briefing, during which most of the women, even the most highly educated ones, never fully understood the research; the subjects felt they had no other choice if they wanted to save their children.

Despite such inducement, the NBAC concluded that it was not enough to curb a subject’s voluntary decision to participate in the research. This is a bold conclusion, considering that both the NBAC and commentators deem informed consent a cornerstone of research ethics and agree that the quality of informed consent can be compromised based on the participant’s beliefs. The NBAC has admitted that its recommendations are only the first step in obtaining voluntary informed consent; however, in order to adequately protect participants, clearer standards are necessary.

B. Placebo v. Best Available Treatment

Despite the clear mandate in Helsinki II that research on human subjects must conform to “generally accepted scientific principles” and

which group they were in.” Questions and Answers, supra note 10.

146. Howard W. French, AIDS Research in Africa: Juggling Risks and Hopes, N.Y. TIMES, Oct. 9, 1997, at A1. Interviews with other women revealed that they did not understand the complexity of the ethical and scientific issues stemming from the research study. Id.
147. Id.
148. Id.
149. Id. Even the American investigators conducting the study were not told all the pertinent details. One researcher reported that he was never told that the same study could not be conducted in the United States. Instead, he was only told that the study was consistent with “the strictest American and international standards for medical research.” Moreover, the investigators were told not to speak about their work. Id.
150. REPORT AND RECOMMENDATIONS, supra note 109, at 47.
151. Ruth Faden & Nancy Kass, HIV Research, Ethics, and the Developing World, 88 AM. J. PUB. HEALTH 548 (1998). (“All too often, a research project offers the best medical care or the only medical care available, and it may be impossible for potential subjects who are ill or at risk to refuse research participation.”)
152. REPORT AND RECOMMENDATIONS, supra note 109, at 51.
more specifically, that any new treatment is to be weighed against the “best current diagnostic and therapeutic methods,” the AZT trials did not meet this standard. Nor did the trials meet the Guidelines’ ethical standard that the treatment be “no less exacting than they would be for research carried out within the initiating country.” Instead a shorter and less effective AZT treatment was given and was only compared to a placebo rather than the full treatment that had been utilized in the United States research trials.

In its report, the NBAC focused on the crucial question of whether a research study that could not ethically be conducted in the sponsoring country, typically a developed country, could ethically be conducted in a developing country. To address this inconsistency, the NBAC proposed the following recommendation:

**Recommendation 2.2:** Researchers and sponsors should design clinical trials that provide members of any control group with an established effective treatment, whether or not such treatment is available in the host country. Any study that would not provide the control group with an established effective treatment should include a justification for using an alternative design.

This recommendation is contrary to Helsinki’s “best current method” and is obviously in conflict with the Guidelines’ requirement that the host country receive the same treatment as the sponsoring country. The NBAC argued that requiring the same treatment leads to “the patently absurd conclusion that a country would somehow be applying a different ethical standard if its rules for prior independent review of research stipulated, for example, a different composition of research ethics committees than that required for United States research.” In other words, the NBAC is concerned that a host country might have more stringent ethical standards than the sponsoring country and, thus, be forced to adhere to substandard requirements. This argument, however, lacks foundation especially when applied to the AZT trials; the developing country has no ethical standards in place, let alone more stringent standards.

153. See supra text accompanying note 81.
154. See supra text accompanying note 92.
155. REPORT AND RECOMMENDATIONS, supra note 109, at 8. It may be unethical for researchers to go abroad and implement studies that would not be permitted in their own countries. “The exportation of research risks, and importation of valuable scientific knowledge, appear not only inequitable, but repetition of the research practices that were strongly condemned at Nuremberg.” Dickens, supra note 2, at 195.
156. REPORT AND RECOMMENDATIONS, supra note 109, Recommendation 2.2, at 28.
157. See supra text accompanying note 89.
158. Id. at 9.
The NBAC also argued that its ethical standard is better than the "best current method" standard because there is discrepancy in the medical field as to what treatment is the best.\textsuperscript{159} Yet, the NBAC conceded that "it can be difficult to determine whether an intervention constitutes an established effective treatment."\textsuperscript{160} Thus, its argument against using the stricter standard in Helsinki II adversely applies to its own recommended standard.

Nonetheless, the NBAC has maintained that its "established effective treatment" standard is "reasonably clear" and "best conveys what is owed to research participants during a study,"\textsuperscript{161} yet agreed that "it would not be ethical to give participants a placebo [if] doing so would pose undue risk to their health or well-being."\textsuperscript{162} Hence, while the NBAC's new ethical standard of treatment is not as strict as current international standards, it may have prevented the death of approximately 1,000 children during the AZT trials\textsuperscript{163} by administering a treatment more effective than a simple placebo.

C. Availability of Treatment after the Research Trials

The NBAC also addressed another critical question in its report: What amount of treatment, if any should be made available to the research subjects and to others in the host country following the study?\textsuperscript{164} The majority of women in developing countries cannot afford the shorter dose of AZT, yet alone the full dosage,\textsuperscript{165} therefore, how can a less effective, low-cost intervention be beneficial to a host country where no one has access to it following the completion of the trial?

Spokesmen from both the NIH and the CDC justify the AZT studies because the results provided information that the host country can use to determine how to make the intervention available after the trials are concluded.\textsuperscript{166} However, this suggestion leads the host country to determine what to do with research results that it did not even conduct. Commentators are outraged at this suggestion: "[W]hat these countries require is not good intentions, but a real plan to deliver the

\textsuperscript{159} Id. at 10. ("NBAC recognizes that there are often many effective treatments for a given condition and that some controversy exists over which may be considered 'best.")

\textsuperscript{160} Id. For example, one population, due to different medical or social resources and conditions, demographics or other characteristics, may react differently to an intervention than another population, thus making it more or less effective. Id.

\textsuperscript{161} Id.

\textsuperscript{162} EXECUTIVE SUMMARY, supra note 1, at iv.

\textsuperscript{163} See supra text accompanying note 30.

\textsuperscript{164} REPORT AND RECOMMENDATIONS, supra note 109, at 12.

\textsuperscript{165} See supra text accompanying note 44.

\textsuperscript{166} Maternal-Fetal HIV Transmission, supra note 47.
intervention."\textsuperscript{167}

In response to this dilemma, the NBAC proposed the following recommendation, as pertinent:

\textit{Recommendation 4.1}: Researchers and sponsors in clinical trials should make reasonable, good faith efforts before the initiation of a trial to secure, at its conclusion, continued access for all participants to needed experimental interventions that have been proven effective for the participants.\textsuperscript{168}

While this recommendation suggests the importance of providing the participants access to the treatment, it does not guarantee delivery of the intervention. The NBAC should mandate that the drug intervention be made available, not leave yet another aspect of the research trials to the discretion of the investigators.\textsuperscript{169} Unless the treatment is made available to the host country, and more importantly, to the research participants, "developed countries are simply exploiting them in order to quickly use the knowledge gained from the clinical trials for the developed countries' own benefit."\textsuperscript{170}

The NBAC proposed \textit{Recommendation 4.1} because the issue of treatment made available after trial completion remained unaddressed by United States guidelines,\textsuperscript{171} yet the NBAC does not adequately solve the issue with its own proposal. Investigators are still left with the discretion to determine what are "reasonable" efforts to ensure treatment, and whether it is made available. In addition, the investigators only have to make a "good faith" effort to implement the intervention(s). The question remains: Who determines whether the sponsor is putting forth a "good effort"? Who is enforcing these regulations?

Some developing countries have bypassed United States and other

\textsuperscript{167} \textit{Id.} It is a relatively common occurrence that even inexpensive and effective treatments are not distributed to those in developing countries, particularly Africa. For example, an inexpensive and effective treatment to reduce the transmission of sexually transmitted diseases was never delivered to rural Tanzania. \textit{Id.}

\textsuperscript{168} \textit{REPORT AND RECOMMENDATIONS, supra} note 109, \textit{Recommendation 4.1}, at 74.

\textsuperscript{169} One researcher from a developing country commented, "'[i]t should be made a requirement that [if developing country] research involving testing of drugs and other interventions [is] found efficacious, the participating populations should be among the first ones to benefit, at affordable costs.'" \textit{REPORT AND RECOMMENDATIONS, supra} note 109, at 56 (quoting Nancy Kass & Adnan A. Hyder, \textit{Attitudes and Experiences of U.S. And Developing Country Investigators Regarding U.S. Human Subjects Regulations}, in II NBAC, ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH: CLINICAL TRIALS IN DEVELOPING COUNTRIES: COMMISSIONED PAPERS AND STAFF ANALYSIS B-1, B-98 (2001)) available at http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

\textsuperscript{170} \textit{Maternal-Fetal HIV Transmission, supra} note 47.

\textsuperscript{171} \textit{REPORT AND RECOMMENDATIONS, supra} note 109, at 55. Thus far, regulations have simply advised that the issue of access is to be discussed prior to the inception of the study. \textit{Id.} at 57.
developed countries by taking the extra step and imposing affirmative obligations on the investigators to provide any effective treatment to the participants, as well as the general population.\footnote{Uganda and Brazil are among the nations to adopt such a requirement. \textit{Id}.}

Unfortunately, once again, the United States has no clear enforcement mechanisms for its research guidelines. In the past, bioethical guidelines failed to provide a source of binding authority,\footnote{See supra text accompanying notes 82, 83.} which resulted in less than acceptable research trials, leaving participants without a remedy. While the NBAC's recommendations address the growing number of crucial ethical issues in international human research, they do not possess the binding authority the world needs to provide adequate protection of the rights and welfare of human beings, primarily in developing countries.

VI. Will Exploitation Continue?

Human research will continue to be an important source of statistical data as incurable diseases and new strains of illnesses entice aggressive companies and governmental agencies to find a cure or a life-saving drug, likely all with human beings acting as guinea pigs.

Those wishing to reach the finish line first may take shortcuts, try to evade national and international regulations and unknowingly or even intentionally compromise a subject's rights along the way. In the past, such violations have raised eyebrows and even spurred the promulgation of legislation to ensure the safety of the human race. Yet, the world has failed to establish enforceable bioethical guidelines that will ensure the protection of human subjects.

Faced with a difficult and narrow task, the NBAC proposed twenty-eight recommendations, addressing potential ethical issues that may arise prior to, during, or even after a human experiment.\footnote{See supra Section V.} In particular, the NBAC focused on ensuring voluntary informed consent is obtained from every participant, effective treatment is administered during the intervention and access to the treatment is given following the completion of the research.

While the NBAC has made great strides to protect human subjects and is commended for its efforts, the recommendations proposed simply fail to provide the binding authority needed to overcome unethical behavior. The potential to exploit human beings, especially those living in developing countries, remains. Investigators are still given discretion in determining the methodology and the amount of information given to research subjects; United States administrative agencies, despite clear
cries from research participants, still maintain that subjects are informed and voluntarily consented to the research; subjects will be given an “established effective treatment” rather than the best available treatment; “good faith” efforts will not meet the demand for inexpensive yet proven treatment; and “minimum standards” will not save the next generation of babies born to HIV infected women in Africa.