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## International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent

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# International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent

By  
Benjamin Mason Meier\*

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\* LL.M. (International and Comparative Law), Cornell Law School; J.D., Cornell Law School; B.A. (Biochemistry), Cornell University. This Article is dedicated to the memory of Ellen Roche—a classmate, a friend, and a victim of medical experimentation. The author wishes to thank Professor David Wippman, Sara Lulo, and Joanne Roman for their thoughtful comments on previous drafts of this Article.

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## I.

### INTRODUCTION

The Nuremberg trials of German medical officers of the Third Reich showed the world the horrors that the Nazi regime perpetrated under the guise of medical experimentation.<sup>1</sup> The atrocities of the Holocaust forced states to recognize that all human subjects of experimentation have certain rights that cannot be infringed—even by physicians. Through the Nuremberg Code and subsequent international regulations, nations, individually and through the United Nations, have attempted to codify a right to free and informed consent in medical experimentation. Despite these international efforts, involuntary medical experimentation<sup>2</sup> continues to present dire human rights abuses throughout the world. This Article addresses violations of the right of informed consent by U.S. physicians conducting human immunodeficiency virus (HIV) vaccine experiments in Africa.

This Article focuses on the right of informed consent to medical experimentation, 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.”<sup>3</sup> Informed consent is “a cardinal principle for judging the propriety of research with human beings.”<sup>4</sup> This principle serves many functions in protecting the rights of sub-

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1. See UNITED STATES V. KARL BRANDT, 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW No. 10 (1948) [hereinafter *Nuremberg Trials*], reprinted in JAY KATZ, EXPERIMENTATION WITH HUMAN BEINGS: THE AUTHORITY OF THE INVESTIGATOR, SUBJECT, PROFESSIONS, AND STATE IN THE HUMAN EXPERIMENTATION PROCESS 293 (1972).

2. For the purposes of this Article, medical experimentation refers to both scientific research and clinical testing, but excludes medical treatments.

3. NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH: CLINICAL TRIALS IN DEVELOPING COUNTRIES, VOLUME I: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 37 (2001) [hereinafter *CLINICAL TRIALS IN DEVELOPING COUNTRIES*].

4. KATZ, *supra* note 1, at 523. The alternative to informed consent is a paternalistic approach to experimentation. Under the paternalistic approach, the physician, rather than the subject, is given the authority to choose what intervention is in the subject's best interest. N.D. Sharma, *Medical Negligence and the Doctrine of Informed Consent*, in GLOBAL HEALTH LAW: PROCEEDINGS, SELECTED PAPERS AND RECOMMENDATIONS PRESENTED AT THE INTER-DISCIPLINARY INTERNATIONAL CONFERENCE ON GLOBAL HEALTH LAW, NEW DELHI, 5-7 DEC., 1997, at 111 (R.K. Nayak ed., 1998). While the paternalistic model of the doctor-patient relationship has been adopted in the United Kingdom, this model has been rejected in the United States, Canada, and Australia in favor of the informed consent model. Even the United Kingdom will soon move to an informed consent model after ratifying the Convention on Human Rights and Biomedicine. See *infra* notes 85-100.

jects of human experimentation.<sup>5</sup> It recognizes and compensates for the inherent conflict of interest between the researcher and human subject.<sup>6</sup> In doing so, informed consent provides both substantive and procedural protections for the subject involved in human research.

Substantively, informed consent provides respect for the subject's autonomy and self-determination.<sup>7</sup> Essentially a right to bodily integrity, informed consent protects "an individual's right to exercise sovereignty over one's body, to be free from assaults upon one's person and from interference with one's biological functions."<sup>8</sup> Professor Hans Jonas placed informed consent in a philosophical context by positing that, through experimentation, the subject is transformed from a living person to a passive, inert object.<sup>9</sup> He argued that "only genuine authenticity of volunteering can possibly redeem the condition of thinghood to which the subject submits."<sup>10</sup>

Procedurally, informed consent protects the interests of the subject where his or her interests conflict with those of the physician. The researcher and the subject have conflicting interests in the experimental setting.<sup>11</sup> Although a physician conducting human experimentation may claim to have the subject's best interests in mind, the physician will also have personal and professional interests

5. KATZ, *supra* note 1, at 523-24, 540-608.

[R]equiring informed consent serves society's desire to respect each individual's autonomy and his right to make choices concerning his own life. Second, providing a subject with information about an experiment and encouraging him to be an active partner in the process may also increase the rationality of the experimentation process. Third, securing informed consent protects the experimentation process by encouraging the investigator to question the value of the proposed project and the adequacy of the measures he has taken to protect subjects . . . Finally, informed consent may serve the function of increasing society's awareness about human research.

*Id.* at 523-24.

6. Frances H. Miller, *Trusting Doctors: Tricky Business When It Comes to Clinical Research*, 81 B.U. L. REV. 423, 436-37 (2001).

7. RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 235 (1986) (noting that "informed consent is rooted in concerns about protecting and enabling autonomous or self determining choice by patients and subjects"); CLINICAL TRIALS IN DEVELOPING COUNTRIES, *supra* note 3, at 35 ("The requirement for freely given and informed consent to participate in research reflects important substantive ethical principles, including respect for persons, human dignity, and autonomy.").

8. Kevin M. King, Note, *A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STAN. J. INT'L L. 163, 174 (1998).

9. Hans Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, 98 DAEDALUS 219, 240 (1969).

10. *Id.*

11. PAUL S. APPELBAUM ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 219 (1987).

Researcher and subject may share some goals—for example, the advancement of knowledge—but are likely to be in conflict about others. . . . Subjects of nonclinical research (in which no treatment is provided) will have a natural interest in avoiding harm. Although researchers will generally share that goal, they may be somewhat more inclined than subjects to take risks in order to generate desired data.

*Id.* at 219-20 (citations omitted); see also GEORGE J. ANNAS, *STANDARD OF CARE: THE LAW OF AMERICAN BIOETHICS* 133-34 (1993) (retelling Gustave Flaubert's novel *Madame Bovary*, in which "Charles Bovary decides to make his name as a physician by curing the local stableman's club foot with experimental surgery").

that may conflict with the subject's interests.<sup>12</sup> Furthermore, physicians acting in a research capacity often disregard the subject's right of free and informed consent "in the belief that [they] can be trusted to safeguard the physical integrity of their subjects."<sup>13</sup> The resulting conflict of interest imposes competing loyalties on the researcher.<sup>14</sup> To prevent this dilemma, informed consent "levels the playing field," providing the subject with the tools necessary to make a decision contrary to the wishes of the physician.<sup>15</sup> By requiring that information be given to the subject, the doctrine of informed consent enables prospective subjects to exercise autonomy when they make decisions about research.<sup>16</sup>

There are many barriers to the comprehension of risk and rational decision-making necessary for informed consent. These barriers are particularly acute in developing nations. The "short course" AZT trials in Africa are a modern example of this problem.<sup>17</sup> In this paradigmatic case, science's quest for a cure has led to the erosion of principles of informed consent and the denigration of individual rights.<sup>18</sup>

Part II of this Article explains the short course AZT trials conducted on HIV-positive African subjects by U.S. physicians. In particular, Part II outlines violations of the research subject's right of informed consent. Part III describes the experiments of Nazi physicians during World War II, the trial of these physicians at Nuremberg, and the Nuremberg Tribunal's development of the Nuremberg Code, the foundation of modern international regulation of human experimentation. Part IV details the development of international regulation of human experimentation following the Nuremberg Code. Part V highlights the weaknesses of these international regulations insofar as they permitted involuntary medical experimentation with HIV-positive subjects in Africa to continue unabated. Part VI recommends the development of an international solution to

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12. Ileana Dominguez-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT'L L.J. 245, 282 (1997) (citing Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 17 (1993)). Professor Katz has found that physicians disregard the doctrine of informed consent, *inter alia*, "to get research underway, advance science, and obtain research grants for the sake of protecting their laboratories and professional advancement." Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now*, in GEORGE J. ANNAS & MICHAEL A. GRODIN, *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* 231 (1992).

13. Katz, *supra* note 12, at 232.

14. Richard Delgado & Helen Leskovic, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67, 91 (1986) ("Conflict of interest rules express the intuitive conviction that persons who occupy positions of trust should not involve themselves in outside obligations or self-interests that could compromise their ability to protect the interests entrusted to them.").

15. Elysa Gordon, Note, *Multiculturalism in Medical Decisionmaking: The Notion of Informed Waiver*, 23 FORDHAM URB. L.J. 1321, 1328 (1996).

16. Miller, *supra* note 6, at 429.

17. See *infra* notes 19-28 and accompanying text.

18. See *infra* notes 29-35 and accompanying text; M. Cheriff Bassiouni et al., *An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation*, 72 J. CRIM. L. & CRIMINOLOGY 1597, 1601 (1981) (citing Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966)) (noting that "[w]hile human experimentation has advanced man's knowledge and improved his life, it has failed to keep pace in the development of the safeguards needed to protect human subjects").

guarantee the right of meaningful informed consent to each subject of medical experimentation and proposes the creation of an international convention for the protection of informed consent.

## II.

### AIDS—LESSONS FROM AFRICA

The horrors of involuntary medical experimentation still exist today. The AIDS epidemic has driven desperate African nations to permit scientists to test experimental vaccines on uninformed and unwilling subjects. This Part discusses the U.S. "short course" AZT vaccine trials in Africa and the ethical and legal issues that arise from them.

With spiraling worldwide infection of HIV in the 1990s,<sup>19</sup> certain members of the scientific community increasingly came to believe that the best way to impede a worldwide AIDS epidemic was through preventive vaccine development.<sup>20</sup> In 1996, scientists in France and the United States determined that the use of Zidovudine (AZT) during the final twenty-six weeks of pregnancy could reduce by two-thirds the chances that a baby would be infected with HIV.<sup>21</sup> However, that specific AZT regimen was found to be prohibitively expensive and complicated for health care systems in developing countries, where AIDS had been felt most acutely. To create a more efficacious means of treating AIDS patients in the developing world, studies attempted to find the minimum amount of AZT needed to block transmission of HIV from mother to child. Among these studies, the "short course"<sup>22</sup> AZT trials tested the efficacy of oral AZT in preventing transmission of HIV from mother to child during pregnancy and childbirth.

The United States began testing short course AZT treatments in Africa<sup>23</sup> in 1994, through which the Centers for Disease Control (CDC) and the National

19. It is estimated that AIDS has killed 21.8 million people, with 3 million dying in 2000. Elizabeth Olson, *AIDS Infections Rise Globally, but Sub-Saharan Cases Stabilize*, N.Y. TIMES, Nov. 25, 2000, at A3. The World Health Organization estimates that 36.1 million adults are currently living with AIDS or HIV, the virus that causes AIDS. *Id.* Of these, 5.3 million became infected with HIV in 2000 alone. *Id.*

20. See Barry R. Bloom, *The Highest Attainable Standard: Ethical Issues in AIDS Vaccines*, SCIENCE, Jan. 9, 1998, at 186. In 1994, AIDS Clinical Trials Group Study 076 showed AZT to be the first vaccine effective in reducing the incidence of HIV infection in children born to HIV-positive mothers. E.M. Connor et al., *Reduction of Maternal-Infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment*, 331 NEW ENG. J. MED. 1173, 1173 (1994).

21. R.S. Sperling et al., *Maternal Viral Load, Zidovudine Treatment, and the Risk of Transmission of Human Immunodeficiency Virus Type 1 from Mother to Infant*, 335 NEW ENG. J. MED. 1621, 1621 (1996). This regimen also requires intravenous flow of AZT for the mother during childbirth and six weeks of oral AZT for the newborn infant. *Id.*

22. "Short course" AZT treatment is given to test subject mothers only in the last four weeks of pregnancy and during labor, rather than the full twenty-six week course. See generally Connor et al., *supra* note 20, at 1173.

23. The testing took place in the Ivory Coast, Uganda, Tanzania, South Africa, Ethiopia, Burkina Faso, Malawi, and Zimbabwe. Michael Brown, *Medical Group Condemns U.S. AIDS Drug Tests in Africa for Using Placebo*, WASH. POST, Apr. 23, 1997, at A14. In addition, some testing took place outside of Africa, in Thailand and the Dominican Republic. Sheryl Gay Stolberg, *U.S. AIDS Research Abroad Sets Off Outcry over Ethics*, N.Y. TIMES, Sept. 18, 1997, at A1.

Institutes of Health (NIH) funded the testing of over 17,000 women.<sup>24</sup> Half of these women received only a placebo.<sup>25</sup> Among the subjects, there was little understanding about the testing or the ethical issues surrounding it, the effectiveness and possible dangers of the vaccine, or the nature of a placebo. Howard French gave a detailed explanation of the consent procedure used with Siata Ouattara, a subject in the study:

Minutes after [Ms. Ouattara] was informed for the first time that she carried the virus, [the] pregnant woman . . . still visibly shaken by the news, was quickly walked through the details of the tests. . . . In less than five minutes, in which the previously unknown concept of a placebo was briefly mentioned, the session was over, and Ms. Ouattara, unemployed and illiterate, had agreed to take part in the tests. Asked what had persuaded her to do so, she responded, "the medical care that they are promising me."<sup>26</sup>

According to Stanford Professor David Katzenstein, who was running AIDS vaccine trials in conjunction with the University of Zimbabwe, "researchers often treat potential volunteers like patients, which means deciding what is best for them and then 'tell[ing] them they are going to give them a medicine.'"<sup>27</sup> In

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24. Peter Lurie & Sidney M. Wolfe, *Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries*, 337 NEW ENG. J. MED. 853, 853 (1997); Stolberg, *supra* note 23, at A1.

25. Aside from informed consent issues, critics have found the short course study additionally unethical based on the use of placebos in research where a proven life-saving regimen already existed. Carol Levine, *Placebos and HIV Lessons Learned*, HASTINGS CENTER REP., Nov.-Dec. 1998, at 43-44. Critics estimate that, in Africa, over 1000 babies contracted HIV because their subject-mothers were given the placebo regimen. Stolberg, *supra* note 23, at A1. An alternative to placebo-controlled trials is an equivalency study, which is used when, as in this case, "a particular regimen has already been proved effective and one is interested in determining whether a second regimen is about as effective but less toxic or expensive." Lurie & Wolfe, *supra* note 24, at 853 (citation omitted). In this situation, an equivalency study would compare the short course AZT treatment with previous AZT treatments already proven effective (a benchmark). In similar trials in the United States, scientists used equivalency studies, i.e., "the patients in all the study groups ha[d] unrestricted access to [AZT] or other antiretroviral drugs." *Id.* at 853-55 (arguing that the United States has created a "double standard" in research ethics).

26. Howard French, *AIDS Research in Africa: Juggling Risks and Hopes*, N.Y. TIMES, Oct. 9, 1997, at A1. Mr. French also interviewed many subjects of the experiments about the scientific value of the research, the ethical issues surrounding the research, and the use of placebos, reporting their accounts:

They gave me a bunch of pills to take and told me how to take them. Some were for malaria, some were for fevers, and some were supposed to be for the virus. I know that there were different kinds, but I figured that if one of them didn't work against AIDS, then one of the other ones would.

I don't remember exactly what they told me. . . . They said that it would help my child, and that it would ease my childbirth too.

I am not sure that I understood all of this so well. But there were some medicines that they said might protect the mother and the child, and they wanted to follow the evolution of my pregnancy and the effectiveness of the treatment. . . . At the time they explained this to me, I asked myself the simple question of whether I had any choice. As long as there was a possibility to save my daughter, I had to try.

*Id.*

27. Rachel Nowak, *Staging Ethical Trials in Africa*, 269 SCIENCE 1332, 1334 (1995). This paternalistic relationship is a far cry from the now increasingly strained doctor-patient relationship in the United States. See Miller, *supra* note 6, at 423 (noting that "many [U.S.] patients suspect that self-interested physicians will . . . persuade them to undergo unnecessary—even sometimes dangerous—therapy").

fact, as noted by Peter Lamprey, a physician from Ghana and head of the AIDS Control and Prevention Program (AIDSCAP), "if you interviewed the people in the study, most wouldn't understand to what they had actually consented."<sup>28</sup>

Although U.S. government agencies were conducting the testing, these experiments took place without regard for U.S. medical research standards, which require, *inter alia*, that patients be fully informed of all possible treatment options and that they receive, at a minimum, the prevailing standard of care.<sup>29</sup> Some U.S. scientific experts quickly denounced the testing as unethical. Sidney Wolfe, director of the Public Citizen Health Research Group, decried the experiments as "unethical as any experiments we have ever seen since the end of the Second World War."<sup>30</sup> Many critics further blasted the study as a racist exploitation of people of color, and based upon the U.S. experience, compared the short course trials in Africa to the Tuskegee syphilis studies.<sup>31</sup>

In addition to conflicting with U.S. law, the AZT experiments took place in violation of international ethical standards. Pursuant to international standards,

28. Nowak, *supra* note 27, at 1334.

29. 45 C.F.R. § 46.101(a) (stating that U.S. bioethics regulations shall apply to "research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States"); see Brown, *supra* note 23, at A14; French, *supra* note 26, at A1 (noting that such testing would not have received approval if it were to take place in the United States); Ronald Bayer, *The Debate over Maternal-Fetal HIV Transmission Prevention Trials in Africa, Asia, and the Caribbean: Racist Exploitation or Exploitation of Racism?*, 88 AM. J. PUB. HEALTH 567, 569 (1998) (suggesting that if such testing had been performed in the United States, there would have been no doubt that it was unethical and illegal); Press Release, Public Citizen, Health Group Files Suit over NIH Experiments on HIV-Positive Women in Developing Countries: NIH Fails to Produce Consent Forms and Other Documents for Unethical Experiments on Pregnant Women (Mar. 18, 1998), at <http://www.citizen.org/press/pr-sid-4.htm>.

30. Brown, *supra* note 23, at A14 (arguing that "the all-placebo arms are unethical because they, in effect, knowingly give experimental subjects substandard care"). *But cf.* AZT Trials in Developing Countries: *What's Next?*, AIDS ALERT, Feb. 1, 1998, at 1 (statement of September Williams that "[t]here is an underlying [false] assumption that folks in Africa in general can't make these types of autonomous decisions, just like there is a similar understanding that folks in Harlem can't do that").

31. *E.g.*, Letter from Peter Lurie et al. to Donna Shalala (Apr. 22, 1997), available at <http://www.citizen.org/publications/release.cfm?ID=6627> ("Many people will hear in these experiments echoes of the notorious Tuskegee syphilis study. . . . This time, the people of color affected are babies from Africa, Asia, and the Caribbean, many hundreds of whom will die unnecessarily in the course of this unethical, exploitative research."). In the Tuskegee syphilis study, the U.S. Public Health Service tracked a group of African American males from the early 1930s into the 1970s to ascertain the course of syphilis if left untreated. This study was carried out despite the existence of a proven treatment for the disease. No informed consent was obtained in the study, and many of the subjects in the study were led to believe that they were receiving treatment. ARNOLD J. ROSOFF, *INFORMED CONSENT, A GUIDE FOR HEALTH CARE PROVIDERS* 258 (1981). In 1996, the United States issued a formal apology for the wrongs of the Tuskegee study. In doing so, President Clinton stated:

It is not only in remembering that shameful past that we can make amends and repair our nation, but it is in remembering that past that we can build a better present and a better future. . . . What is done cannot be undone. But we can end the silence. We can stop turning our heads away. We can look at you in the eye and finally say on behalf of the American people, what the United States government did was shameful. . . . I am sorry that your federal government orchestrated a study so clearly racist. That can never be allowed to happen again.

William J. Clinton, *Remarks by the President in Apology for Study Done in Tuskegee* (May 16, 1996), reprinted in SUSAN M. REVERBY, *TUSKEGEE'S TRUTHS* 574-75 (2000).



it is clear that the subjects were neither sufficiently informed nor did they freely consent.<sup>32</sup> The Nuremberg Code guarantees that subjects “should be so situated as to be able to exercise free power of choice.”<sup>33</sup> However, the very nature of the subjects’ life-threatening disease, their low education, the researchers’ offers of payment, and the lack of alternate medical options denied these subjects the ability to make an informed choice, and therefore made any consent obtained from them purely “illusory.”<sup>34</sup> These experiments also took place in violation of the Helsinki Declaration’s informed consent standards, specifically those which provide that “ethical standards applied [abroad] should be no less exacting than they would be in the case of research carried out in [the sponsoring] country.”<sup>35</sup>

The African short course AZT testing has ended. In early 1998, the CDC announced that it would no longer continue the short course AZT trials in developing countries, stating that experiments in Thailand had yielded sufficient data.<sup>36</sup> However, although the short course AZT trials have ended, human experimentation in developing countries—African countries in particular—has continued.<sup>37</sup> Entrepreneurial scientific corporations, whose financial interests often do not align with the interests of their research subjects,<sup>38</sup> are expanding into new markets. With increased globalization of trade, scientific acceptance of foreign data, and greater attention paid by developed nations to the hazards

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32. Professor Lawrence Gostin, who co-authored a survey of physicians for the Office for Protection of Research Risks, summarized that “[i]t’s obvious that not everyone is rigorously following individual consent procedures.” Nowak, *supra* note 27, at 1332.

33. Nuremberg Code, reprinted in ANNAS & GRODIN, *supra* note 12, at 2.

34. Jay Dyckman, *The Myth of Informed Consent: An Analysis of the Doctrine of Informed Consent and Its (Mis)Application in HIV Experiments on Pregnant Women in Developing Countries*, 91 COLUM. J. GENDER & L. 91, 94 (1999). “Offering a chance of free health care to indigent, pregnant HIV-positive women compels a reanalysis of how the often illusory qualities of consent are manifested in medical experimentation on relatively unempowered subjects.” *Id.* at 98; Nowak, *supra* note 27, at 1334 (noting that many African subjects participated in studies simply for food or money).

35. Declaration of Helsinki, WMA 29th Assembly (Oct. 1975), reprinted in ANNAS & GRODIN, *supra* note 12, at 333 [hereinafter 1975 Declaration of Helsinki].

36. Sheryl Gay Stolberg, *Placebo Use Is Suspended in Overseas AIDS Trials*, N.Y. TIMES, Feb. 18, 1998, at A16. For the results of the Thailand Study, see generally *Administration of Zidovudine During Late Pregnancy and Delivery to Prevent Perinatal HIV Transmission—Thailand 1996-1998*, 47 MORBIDITY & MORTALITY WKLY. REP. 151 (1998).

37. For a list of recent collaborative AIDS studies in Africa, see Nowak, *supra* note 27, at 1332.

38. See Joe A. Flores, *International Scientific Misconduct and the Legal System*, 9 CURRENTS: INT’L TRADE L.J. 60, 62 (2000) (noting “a shift from autonomous research to that of commercially funded capitalist goal-directed research”); Miller, *supra* note 6, at 429; see also Nancy Kass & Adnan Hyder, *Attitudes and Experiences of U.S. and Developing Country Investigators Regarding U.S. Human Subjects Regulations*, in NAT’L BIOETHICS ADVISORY COMM’N, ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH: CLINICAL TRIALS IN DEVELOPING COUNTRIES, VOLUME II: COMMISSIONED PAPERS AND STAFF ANALYSIS, at B-1, B-32 (2001) [hereinafter CLINICAL TRIALS IN DEVELOPING COUNTRIES II] (“It’s not a charitable business. It’s Wall Street hardcore business. And doing clinical trials in the third world sometimes may be motivated by . . . access to the patient in large numbers and a faster rate. And sometimes the third argument, nevertheless, is also at a cheaper price.” (quoting an anonymous researcher)).

posed by “emerging infections,” studies in developing countries will be a major part of future research efforts.<sup>39</sup>

### III.

#### JUDGMENT AT NUREMBERG—HUMAN EXPERIMENTATION ON TRIAL

The prosecution of Nazi physicians in the aftermath of the Second World War represented the first international condemnation of medical research. Through this prosecution, the Nuremberg Tribunal developed the Nuremberg Code, which laid down informed consent as the foundation of all ethical research with human subjects. This Part explores the Nazi experiments, the trial of Nazi physicians in the so-called Doctors’ Trial, and the emergence of the Nuremberg Code as an international standard to protect a subject’s right of informed consent.

#### A. *World War II*<sup>40</sup>

The Nazi atrocities, and human experimentation derived from them, constitute a complete disregard for the value of human life and the inherent rights of the test subject.<sup>41</sup> German doctors, led by Dr. Karl Brandt, performed fatal experiments on otherwise healthy patients.<sup>42</sup> In the aftermath of the war, it was found that Nazi researchers took part in “medical experiments without the subjects’ consent, upon civilians and members of the armed forces of nations then at war with the German Reich . . . in the course of which experiments the[y] committed murders, brutalities, cruelties, tortures, atrocities, and other inhuman acts.”<sup>43</sup> These experiments included freezing experiments (subjects were forced to remain in a tank of ice water for periods up to 3 hours), malaria experiments (subjects were deliberately infected with malaria to investigate immunization procedures), sulfanilamide experiments (subjects were deliberately wounded and then infected with bacteria such as streptococcus, gas gangrene, and tetanus), typhus experiments (subjects were deliberately infected with spotted fever virus merely to keep the virus alive), and poison experiments (subjects were deliberately shot with poisoned bullets and then killed immediately to permit autop-

39. *Sounding Board*, 337 NEW ENG. J. MED. 853 (1997); Dominguez-Urban, *supra* note 12, at 267-68, 275 (analyzing the necessity of research in developing countries).

40. For a historical survey of human experimentation prior to World War II, see generally Bassiouni et al., *supra* note 18, at 1598-1600.

41. See Telford Taylor, *Opening Statement of the Prosecution, December 9, 1946*, reprinted in ANNAS & GRODIN, *supra* note 12, at 67 (“The defendants in this case are charged with murders, tortures, and other atrocities committed in the name of medical science. . . . To their murderers, these wretched people were not individuals at all. They came in wholesale lots and were treated worse than animals.”).

42. Ironically, although many Jews escaped the Holocaust, not all were able to escape involuntary medical experimentation. At least one report claims that British physicians deliberately infected Jewish refugees with malaria while interned in refugee camps in Australia. The British purportedly conducted these experiments in an effort to create a vaccine to protect British soldiers fighting on the Pacific front. See Elli Wohlgelemler, *Report: Australian Army Experimented on Jews in WWII*, JERUSALEM POST, Apr. 20, 1999, at 1.

43. Nuremberg Trials, *supra* note 1, at 296.

sies).<sup>44</sup> The subjects of these experiments were prisoners in concentration camps, who neither benefited from such treatments nor gave voluntary consent to them.<sup>45</sup>

The experiments of the Nazi doctors were scientifically worthless.<sup>46</sup> The prosecution in the Doctors' Trial dispelled all scientific aspects of the Nazi research:

The Nazis have, to a certain extent, succeeded in convincing the peoples of the world that the Nazi system, although ruthless, was absolutely efficient; that although savage, it was completely scientific; that although entirely devoid of humanity, it is highly systematic—that "it got things done." The evidence which this Tribunal will hear will explode this myth. The Nazi methods of investigation were inefficient and unscientific, and their techniques of research were unsystematic.<sup>47</sup>

Thereby, "the greatest of all medical tragedies was further magnified by the fact that the experiments performed added nothing of significance to medical knowledge."<sup>48</sup>

The silence of the German doctors and the breakdown of ethical protections in the face of such atrocities amounted to complicity by the entire German medical profession.<sup>49</sup> "[F]ar from opposing the Nazi state militantly, part of the German medical profession cooperated consciously and even willingly, while the remainder acquiesced in silence."<sup>50</sup> Thus, the Nazi infamy was not merely the infamy of a few crazed, psychologically-twisted practitioners. Far from it, over two hundred German physicians participated directly in the medical war crimes and several hundred more were aware of what was happening.<sup>51</sup> Few physicians were without blame.

### *B. The Doctors' Trial*

The trial of Nazi physicians in the aftermath of World War II focused on twenty-three defendants in a trial lasting 139 days. The Nuremberg Military

44. *See id.* at 294-96.

45. *See id.* at 297 ("None of the victims of the atrocities perpetrated by these defendants were volunteers, and this is true regardless of what these unfortunate people may have said or signed before their tortures began." (quoting opening statement of the prosecution by Brigadier General Telford Taylor)).

46. Andrew C. Ivy (Medical Scientific Consultant to the Prosecution, Military Tribunal No. 1, Nuremberg), *Statement*, in ALEXANDER MITSCHERLICH, *DOCTORS OF INFAMY: THE STORY OF THE NAZI MEDICAL CRIMES* xii (Heinz Norden trans., 1949).

47. MITSCHERLICH, *supra* note 46, at xix-xx (quoting opening statement of the prosecution by U.S. Supreme Court Justice Robert Jackson).

48. Ivy, *supra* note 46, at xii.

49. *Id.* at x.

50. *Id.* at xi.

51. *Id.* at x.

What happened to the medical profession of Germany is stern testimony to the fact that acceptance of or even silence before anti-Semitism and the rest of the trappings of racism, acquiescence in or even silence before the violation of sacred professional ethics, the service by medical men of any goal but truth for the good of humanity, can lead to dishonor and crime in which the entire medical profession of a country must in the last analysis be considered an accomplice.

*Id.* at xii-xiii.

Tribunal found that "beginning with the outbreak of World War II criminal medical experiments on non-German nationals, both prisoners of war and civilians, including Jews and 'asocial' persons, were carried out on a large scale in Germany and the occupied countries."<sup>52</sup> The Tribunal's verdict in *United States v. Karl Brandt* found that several of the doctors had committed war crimes and crimes against humanity.<sup>53</sup> The Tribunal noted that "[i]n every single instance appearing in the record, subjects were used who did not consent to the experiments; indeed, as to some of the experiments, it is not even contended by the defendants that the subjects occupied the status of volunteers."<sup>54</sup> The Tribunal found sixteen physicians and scientists guilty and sentenced seven to death.<sup>55</sup>

### C. Nuremberg Code

The standards on medical experimentation laid out by the Nuremberg Tribunal in *United States v. Karl Brandt* have come to be known as the Nuremberg Code. Although not a binding international treaty, the Nuremberg Code became the first international standard defining permissible medical experiments.<sup>56</sup> Two of the ten principles of the Code deal with informed consent. The first principle of the Code specifies that "to satisfy moral, ethical, and legal concepts . . . the voluntary consent of the human subject is absolutely essential."<sup>57</sup> The

52. Nuremberg Trials, *supra* note 1, at 296.

53. *Id.*

War crimes encompass violations of the laws and customs of war. Crimes against humanity include murder, extermination, enslavement, deportation, and other inhumane acts committed against any civilian population, before or during a war, or persecutions on political, racial or religious grounds in execution of or in connection with any crime within the jurisdiction of the Tribunal, whether or not in violation of the domestic law of the country where perpetrated.

Charter of the International Military Tribunal, Aug. 8, 1945, art. 2, 82 U.N.T.S. 280 (defining war crimes and crimes against humanity); Bassiouni et al., *supra* note 18, at 1640.

54. Nuremberg Trials, *supra* note 1, at 296.

55. In addition, there were nine sentences of confinement and eight acquittals. ANNAS & GRODIN, *supra* note 12, at 120. Of the nine sentenced to prison terms, all had their sentences commuted to sentences of no more than twenty years. *Id.*

56. APPELBAUM ET AL., *supra* note 11, at 212 (noting that "[p]rior to World War II, little attention was paid to the circumstances under which research should be carried out, including the issue of consent").

57. Nuremberg Code, *supra* note 33, at 2. The first principle, in full, requires that:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

judges went on in great detail in the first principle to define voluntary consent and the disclosures that physicians must provide before obtaining that consent. In addition, the Code requires in principle nine that the subject have the right to terminate participation “if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.”<sup>58</sup> The Nuremberg Code left little room for doubt as to what was—and what was not—permissible medical research.

#### IV.

##### DEVELOPING INTERNATIONAL REGULATION OF INFORMED CONSENT

Prior to the Doctors’ Trial, physicians and scientists relied only upon their own moral judgment and their interpretation of the Hippocratic Oath.<sup>59</sup> Although many viewed the Nuremberg Code as the first source of international law regulating human experimentation, the Code had little impact on worldwide research practices, as it was not binding under the law of individual states.<sup>60</sup> Further, Western physicians criticized the Nuremberg Code as unnecessarily limiting ethical medical research.<sup>61</sup> Physicians considered the Nuremberg Code “too uncompromising and too inhospitable to the advancement of science” and disregarded its significance to other Western research practices.<sup>62</sup> As such, scientists and physicians conducting research throughout the world continued to use human subjects in medical experiments without their knowledge or consent.<sup>63</sup>

However, even though the Nuremberg Code itself did little to improve the state of human experimentation, it nevertheless was the impetus for widespread discussion and formulation of future international guidelines concerning human experimentation.<sup>64</sup> This Part discusses the development of these medical guidelines, focusing on their treatment of informed consent in the conduct of human experimentation.

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*Id.*

58. *Id.* (emphasis added).

59. Bassiouni et al., *supra* note 18, at 1639. For an explanation of the Hippocratic Oath, see *infra* note 102.

60. APPELBAUM ET AL., *supra* note 11, at 213; see also Katz, *supra* note 12, at 228 (noting that physicians viewed the Nuremberg Code as a response applicable only to the Nazi “aberration” in medical experimentation); Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 170 (1998) (noting the lack of response to the Nuremberg Code in the U.S. scientific community).

61. Bassiouni et al., *supra* note 18, at 1641.

Questions have also been raised as to the desirability of informing the subject of all available information, the inability to inform him completely of the risks of the experiment because of the uncertain nature of the experiment, and the legal capacity of normal healthy volunteers (such as prisoners, students, or assistants) to give consent in certain experiments and under certain conditions.

*Id.*

62. Katz, *supra* note 12, at 235.

63. See generally HENRY K. BEECHER, *RESEARCH AND THE INDIVIDUAL: HUMAN STUDIES* (1970); M.H. PAPPERT, *HUMAN GUINEA PIGS: EXPERIMENTATION ON MAN* (1968).

64. Bassiouni et al., *supra* note 18, at 1639.

### A. Declaration of Helsinki

The Declaration of Helsinki<sup>65</sup> was the first international regulation written by physicians for physicians.<sup>66</sup> This attempt at nonbinding self-regulation moved away from the rigid requirements of the Nuremberg Code, recognizing that, at least for clinical research, “it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity.”<sup>67</sup>

The Declaration of Helsinki lays out the basic principle that

[i]n any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time.<sup>68</sup>

The Declaration further requires that “the subject’s freely given informed consent” should be obtained, “preferably in writing.”<sup>69</sup>

The Declaration was amended with regard to vulnerable subjects to require that the physician be particularly cautious if the subject is in a dependent relationship with the physician or may give consent under duress. In the case of experimentation with vulnerable subjects, the Declaration recommends that informed consent be obtained by a doctor who is not engaged in the experiment in any way and who is completely independent from the research.<sup>70</sup> However, these amendments retain the language that

[i]n case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is

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65. Declaration of Helsinki, WMA 52nd Assembly (Oct. 2000), available at [www.wma.net/e/policy/17-c\\_e.html](http://www.wma.net/e/policy/17-c_e.html) [hereinafter 2000 Declaration of Helsinki]; Declaration of Helsinki, WMA 41st Assembly (Sept. 1989), reprinted in ANNAS & GRODIN, *supra* note 12, at 339-42 [hereinafter 1989 Declaration of Helsinki]; Declaration of Helsinki, WMA 35th Assembly (Oct. 1983), reprinted in 30 WORLD MED. J. inside front cover (1984) [hereinafter 1983 Declaration of Helsinki]; Declaration of Helsinki, WMA 35th Assembly (Oct. 1983), reprinted in 30 WORLD MED. J. inside front cover (1984) [hereinafter 1983 Declaration of Helsinki]; 1975 Declaration of Helsinki, *supra* note 35; Declaration of Helsinki, WMA 18th Assembly (June 1964), reprinted in 8 WORLD MED. J. 281 (1964) [hereinafter 1964 Declaration of Helsinki].

66. Prior to the Declaration of Helsinki, the World Medical Association adopted the Principles for Those in Research and Experimentation, which include the principle that “informed consent must be in writing for experimentation on both sick and healthy patients.” World Medical Association, *Principles for Those in Research and Experimentation*, 2 WORLD MED. J. 14 (1955) [hereinafter WMA Principles]. The WMA Principles, like the Nuremberg Code, specifically state that they are binding on physicians, as compared with subsequent international standards, which state that they merely serve as recommendations. Bernard Dickens, *The Challenge of Equivalent Protection*, in CLINICAL TRIALS IN DEVELOPING COUNTRIES II, *supra* note 38, at A-1, A-3 (2001).

67. 1964 Declaration of Helsinki, *supra* note 65, Introduction; see also Richard W. Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW. 455, 474 (1996) (noting that “the Declaration exudes faith in the methods and goals of medical science and accepts the premise that progress requires human subjects”).

68. 1964 Declaration of Helsinki, *supra* note 65, § I.9.

69. *Id.*

70. 1989 Declaration of Helsinki, *supra* note 65, § I.10.

a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.<sup>71</sup>

In effect, the Declaration relaxes the rights of certain vulnerable populations as compared with the Nuremberg Code, thereby permitting experimentation with legally or physically handicapped persons simply if a legal guardian has given consent.

In its most drastic move away from the Nuremberg Code, the Declaration of Helsinki distinguishes between "clinical research combined with patient care" and "non-therapeutic clinical research." In only the latter does the Declaration require that the subject have "free consent after he has been fully informed."<sup>72</sup> Thus, for clinical research combined with patient care,<sup>73</sup>

[t]he qualifying phrases leave considerable room for researchers to decide that they need not obtain consent in a particular case. . . . [B]y permitting consent to be foregone in "clinical research combined with patient care," the declaration endorsed a standard that fell below the historic common-law standard for consent to treatment.<sup>74</sup>

As a result, a researcher need not obtain consent at all in a clinical setting where the researcher believes that it is unnecessary or difficult to obtain.

In spite of the provisions discussed above, the Declaration was not entirely detrimental to the right of informed consent. To protect the consent process, the Declaration was amended to provide for the review of research protocols by an independent committee.<sup>75</sup> Although such a committee has no clear authority to reject research protocols, the peer review component of the Declaration nevertheless represented a novel improvement over the Nuremberg Code, permitting the consent process to be subject to review by those independent from both the researcher and the sponsor.<sup>76</sup>

## B. CIOMS Guidelines

The World Health Organization and Council of the International Organization of Medical Societies (CIOMS) intended the International Ethical Guidelines

71. 1964 Declaration of Helsinki, *supra* note 65, § I.11.

72. *Id.* §§ II-III. Tragically, this same argument was advanced by Dr. Karl Brandt before the Nuremberg Tribunal:

Mr. McHaney: Well, Herr Brandt, why do you draw a distinction between the type of experiments? What difference does it make what type of experiment it is, if the experimental subject has not consented to undergo the experiment?

Defendant Karl Brandt: You may well call it an experiment even when it is only a matter of testing some newly introduced drug. There is the conviction that it will be helpful, but the final knowledge is lacking.

MITSCHERLICH, *supra* note 46, at 156 (cross-examination of Dr. Karl Brandt by the prosecution).

73. 1964 Declaration of Helsinki, *supra* note 65, § II. This language was based on a statement of the British Medical Research Council, which previously had eliminated the requirement of informed consent in experimentation likely to benefit the subject in the United Kingdom's national code. See *British Medical Research Council: Memorandum on Clinical Investigations*, in *CLINICAL INVESTIGATION IN MEDICINE: LEGAL, ETHICAL AND MORAL ASPECTS* 152-54 (1963).

74. APPELBAUM ET AL., *supra* note 11, at 214-15.

75. 2000 Declaration of Helsinki, *supra* note 65, § 13.

76. *Id.*

for Biomedical Research Involving Human Subjects (CIOMS Guidelines)<sup>77</sup> to serve as a model for states drafting national legislation on human research.<sup>78</sup> The CIOMS Guidelines, published in 1982, expand the independent review component of the Helsinki Declaration: Rather than having review committees serve merely to provide comment, the CIOMS Guidelines grant independent ethical review committees the authority to approve or reject research protocols.<sup>79</sup>

In addition, the CIOMS Guidelines surpass the Helsinki Declaration in their protection of vulnerable populations, specifically enumerating pregnant and nursing women, prisoners, children, and persons with mental or behavioral disorders as vulnerable to nonconsensual experimentation.<sup>80</sup>

The CIOMS Guidelines are the first to regulate specifically how researchers funded by developed countries perform experiments with subjects in developing nations.<sup>81</sup> First, they require "that research subjects from developing communities not be used in research that could be carried out reasonably well with subjects from developed countries."<sup>82</sup> Second, they provide that research be responsive to the health needs of the community in which the research is to take place.<sup>83</sup> Lastly, the CIOMS Guidelines require that externally funded research obtain approval from ethical review committees in both the home and host states.<sup>84</sup>

### C. *Convention on Human Rights and Biomedicine*

In response to burgeoning biotechnology research, in particular advances in cloning technology, the Council of Europe drafted the Convention on Human

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77. International Ethical Guidelines for Biomedical Research Involving Human Subjects [hereinafter CIOMS Guidelines], reprinted in *ETHICS AND RESEARCH ON HUMAN SUBJECTS: INTERNATIONAL GUIDELINES* (Z. Bankowski & R.J. Levine eds., 1993) [hereinafter *ETHICS AND RESEARCH ON HUMAN SUBJECTS*].

78. Z. Bankowski et al., *Ethics Standards for Research Across Nations and Cultures*, in *INTERNATIONAL SUMMIT CONFERENCE ON BIOETHICS, TOWARDS AN INTERNATIONAL ETHIC FOR RESEARCH WITH HUMAN BEINGS* 228, 228 (1987) (noting that the CIOMS Guidelines were created "to demonstrate how [the Helsinki] principles could be applied in practice, having regard to differing socioeconomic circumstances, varying national legal provisions and administrative arrangements").

79. CIOMS Guidelines, *supra* note 77, Guideline 3. Guideline 3 states:

An external sponsoring agency should submit the research protocol to ethical and scientific review according to the standards of the country of the sponsoring agency, and the ethical standards applied should be no less exacting than they would be in the case of research carried out in the sponsoring country.

*Id.*

80. *Id.* at Guidelines 6-9. The CIOMS Guidelines define vulnerable populations to protect those who have "a substantial incapacity to protect [their] own interest owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group." *Id.* at Guideline 11.

81. The CIOMS Guidelines define externally sponsored research as "research undertaken in a host country but sponsored, financed, and sometimes wholly or partly carried out by an external international or national agency." *Id.* at Guideline 15.

82. King, *supra* note 8, at 183 (citing CIOMS Guidelines, *supra* note 77, Guideline 8).

83. *Id.*

84. *Id.*



Rights and Biomedicine (CHRB)<sup>85</sup> to reassert the primacy of the individual over the interests of science.<sup>86</sup> In April 1997, the CHRB became the first legally binding international treaty to govern human experimentation.<sup>87</sup>

Article 5 of the CHRB lays out the general rule for informed consent in research,<sup>88</sup> requiring that the subject receive appropriate information as to the "purpose and nature of the intervention as well as on its consequences and risks."<sup>89</sup> It further provides the subject the right to withdraw from an experiment at any time.<sup>90</sup> This general rule was intended to provide a clear informed consent standard, and thereby "to restrain the paternalist approach which might ignore the wish of the patient."<sup>91</sup> The CHRB further contains more restrictive consent requirements for non-therapeutic research. Article 16 provides that "[r]esearch on a person may only be undertaken if . . . (v) the necessary consent as provided for under article 5 has been given expressly, specifically and is documented."<sup>92</sup>

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85. Council of Europe, Convention on Human Rights and Biomedicine, *reprinted in* 36 I.L.M. 817, 821 (1997) [hereinafter CHRB].

86. *Id.* at art. 2 (providing that "[t]he interests and welfare of the human being shall prevail over the sole interests of society or science"). The Convention states that its object and purpose is to "protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine." *Id.* at art. 1. For a discussion of the events leading to the creation of the CHRB, see Marc Ernest Trigilio, Note, *The Convention on Human Rights and Biomedicine: Allowing Medical Treatment and Research Without Consent on Persons Unable to Give Informed Consent*, 22 SUFFOLK TRANSNAT'L L. REV. 641, 646-50 (1999).

87. Trigilio, *supra* note 86, at 655-56. Article 1(2) of the CHRB requires each state party to give effect to the Convention's provisions in its domestic law. CHRB, *supra* note 85, art. 1(2); see also Eibe Riedel, *Global Responsibilities and Bioethics: Reflections on the Council of Europe's Bioethics Convention*, 5 IND. J. GLOBAL LEGAL STUD. 179, 182-83 (noting that some of the articles are framed as self-executing and can be applied even in the absence of domestic law). The following members of the Council of Europe have signed the CHRB: Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Iceland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Moldova, Netherlands, Norway, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, and Ukraine. Council of Europe, *Chart of Signatures and Ratifications* (visited Aug. 30, 2002), at <http://conventions.coe.int/treaty/EN/cadreprincipal.htm>. To date, thirteen member states have ratified the CHRB. *Id.*

88. Article 5 merely states the well-established international rule that no subject may be forced to undergo an experiment without his or her consent. Council of Europe, *Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, ¶ 34, *reprinted in* 36 I.L.M. 817, 830 (1997) [hereinafter *Explanatory Report: Convention on Human Rights and Biomedicine*].

89. CHRB, *supra* note 85, art. 5. "Moreover, this information must be sufficiently clear and suitably worded for the person who is to undergo the intervention." *Explanatory Report: Convention on Human Rights and Biomedicine*, *supra* note 88, ¶ 36.

90. CHRB, *supra* note 85, art. 5.

91. *Explanatory Report: Convention on Human Rights and Biomedicine*, *supra* note 88, ¶ 34. Although the CHRB does permit the physician to avoid the article 5 requirements of informed consent, this is permitted only where a physician is acting without consent for the direct benefit of the subject and consent is not practicable. CHRB, *supra* note 85, art. 6(1).

92. CHRB, *supra* note 85, art. 16; see also *Explanatory Report: Convention on Human Rights and Biomedicine*, *supra* note 88, ¶ 102 ("The words 'specific consent' are to be understood here as meaning consent which is given to one particular intervention carried out in the framework of research.").

The CHRB is the first binding international agreement to address the unique vulnerability of specific populations.<sup>93</sup> The drafters of the CHRB considered subjects in vulnerable populations to be inherently incapable of giving consent.<sup>94</sup> As such, the CHRB severely curtails non-therapeutic research with vulnerable populations.<sup>95</sup> However, article 17(2) provides an exception to the protection of vulnerable populations, allowing non-therapeutic research with subjects incapable of giving consent where

- i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition [and]
- ii. the research entails only minimal risk and minimal burden for the individual concerned.<sup>96</sup>

This exception is justified simply by noting that the population concerned, not the individual, may in the end benefit from the research.<sup>97</sup> In effect, this provision adopts the U.S. position that "if the experimentation is minimally risky or troublesome, then it is acceptable to proceed."<sup>98</sup>

Beyond individual consent, the CHRB protects the autonomy of subjects by requiring peer review by an independent multidisciplinary ethics committee.<sup>99</sup> This committee is to examine the ethical and legal acceptability of the research protocol before research is undertaken.<sup>100</sup>

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93. Trigilio, *supra* note 86, at 643. In addition to those populations specifically mentioned in the Convention, the CHRB defers to each member state's domestic law to define populations as vulnerable. *Explanatory Report: Convention on Human Rights and Biomedicine*, *supra* note 88, ¶ 42.

94. *Explanatory Report: Convention on Human Rights and Biomedicine*, *supra* note 88, ¶ 103.

95. CHRB, *supra* note 85, art. 6 (recognizing that "an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit"). For minors and adults with a mental disability or disease, an experiment "may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law." *Id.*

96. *Id.* at art. 17(2).

97. *Explanatory Report: Convention on Human Rights and Biomedicine*, *supra* note 88, ¶ 107 ("Were such research to be banned altogether, progress in the battles to maintain and improve health and to combat diseases against diseases only afflicting children, mentally disabled persons or persons suffering from senile dementia, would become impossible."). Others have noted that nonconsensual research simply for the benefit of others—even those in a similar population—violates the CHRB's basic purpose of placing the interests of the human being over the interests of science or society. Trigilio, *supra* note 86, at 657.

98. Kevin McDonnell, *Medical Research and Dependent People*, TWENTIETH WORLD CONGRESS OF PHILOSOPHY, Aug. 10-15, 1998, at 4, available at <http://www.bu.edu/wcp/Papers/Bioe/BioeMcDo.htm>.

99. *Explanatory Report of the Convention on Human Rights and Biomedicine*, *supra* note 88, ¶¶ 100, 108.

100. *Id.*

## V.

VIOLATIONS OF INFORMED CONSENT IN AFRICA HIGHLIGHT THE  
WEAKNESS OF INTERNATIONAL REGULATION

There was no developed international law to govern the short course AZT trials that took place in Africa.<sup>101</sup> As such, the research was left to be governed by nonlegal ethical codes and weak national legislation. This Part discusses the weaknesses of these ethical codes, African national laws, and international law, all of which were unsuccessful in protecting the African subject's right of informed consent.

A. *Physicians Cannot Police Physicians*

The medical profession has been shown not to have the ability to police itself.<sup>102</sup> Although physicians have formed international medical organizations to promote medical responsibility, there is no evidence to suggest that these organizations have regulated physician behavior or protected the rights of subjects to free and informed consent.

Physicians from thirty-two national medical associations met in London in 1946 to form the World Medical Association (WMA), the first truly international organization of physicians. Although the WMA quickly "condemned the crimes and inhumanity committed by doctors in Germany and elsewhere against human beings,"<sup>103</sup> it soon thereafter established the potentially conflicting objective of "protect[ing] the interests of the medical profession."<sup>104</sup>

The WMA has repeatedly shown its primary goal to be the protection of physicians, not the protection of patients. The WMA "has never sought or exercised any authority to identify, monitor, or punish either physicians or medical societies who violate their ethical principles."<sup>105</sup> In 1964, the WMA ratified the Declaration of Helsinki, which shifted the focus of human rights from the informed consent standard to a standard of physician responsibility. As noted in Part IV.A, this physician-based approach to patient welfare divided research into two types, requiring consent for non-therapeutic research but not for research combined with professional care. The WMA thus attempted to undermine sub-

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101. See *supra* Part II.

102. In addition, physician oaths, as a means of personal self-regulation, have no effect on physician behavior. Although physicians have taken oaths, often expressed in the form of written codes, since before 2000 B.C., these codes have not hindered violations of patient rights. The most famous and lasting of these codes is the Oath of Hippocrates, which remains the basis of modern U.S. oaths taken by medical school graduates. See generally M.B. ETZIONY, *THE PHYSICIAN'S CREED* 13 (1973). For a brief history of physician oaths, see David A Frenkel, *Human Experimentation: Codes of Ethics*, 1 *LEG. MED. Q.* 7, 7-8 (1977). Ironically, prior to World War II, the Berlin medical school was the only school whose graduates took any oath that forbade risking the lives of patients or subjects "by vain experiment, or doubtful means." ETZIONY, *supra*, at 63.

103. Editorial, 1 *WORLD MED. ASS'N BULL.* 3, 14 (1949).

104. T.C. Routley, *Aims and Objects of the World Medical Association*, 1 *WORLD MED. ASS'N BULL.* 18, 19 (1949). Nowhere do the WMA's objectives list the policing of physicians as an objective of the organization. See *id.*

105. GEORGE J. ANNAS, *SOME CHOICE: LAW, MEDICINE, AND THE MARKET* 251 (1998).

ject consent in the Nuremberg Code and displace it with paternalistic notions of the physician-subject relationship.<sup>106</sup>

In 1992, the WMA further lost moral credibility<sup>107</sup> by electing Hans-Joachim Sewering, a former Nazi physician, as its president.<sup>108</sup> Dr. Sewering resigned as president of the WMA only when the American Medical Association produced documents that actually showed his personal involvement in the Nazi euthanasia experiments with the mentally ill.<sup>109</sup> As noted by Professor George Annas, "[i]f electing a Nazi physician involved in the euthanasia program as president does not disqualify an organization to set the ethical standards for the world's physicians, what would?"<sup>110</sup>

### *B. International Codes of Ethics Have No Effect on Physician Behavior*

The Nuremberg Code, Helsinki Declaration, and CIOMS Guidelines are not legally binding documents capable of placing legally enforceable obligations on states or individuals.<sup>111</sup> They are not widely accepted or followed by physicians.<sup>112</sup> Because they have no enforcement mechanisms, legal or medical, they have little effect on the regulation of human research.

Both the Nuremberg Code and Helsinki Declaration "lack specificity and are therefore susceptible to definition and interpretation by the investigator according to his own experiences."<sup>113</sup> Further, the language of the Nuremberg Code, that "[t]he voluntary consent of the human subject is *absolutely* essential," was fatally weakened by the Declaration of Helsinki. Whereas the Nuremberg Code explicitly banned experimentation with incompetent persons and other persons unable to provide legally valid consent, the Declaration of Helsinki relaxed this by permitting the substitute consent of a legal guardian.<sup>114</sup> The Dec-

106. *Id.*

107. The WMA had previously lost credibility by failing to take a stance regarding apartheid practices in South Africa. George J. Annas & Michael A. Grodin, *Where Do We Go from Here?*, in ANNAS & GRODIN, *supra* note 12, at 312.

108. ANNAS, *supra* note 105, at 251-52. Although Dr. Sewering claims no knowledge of or involvement in the Nazi euthanasia program, there is substantial evidence to the contrary. *Id.*

109. Michael Franzblau, *Investigate Nazi Ties of German Doctor*, S.F. CHRON., Dec. 29, 1993, at A17.

110. ANNAS, *supra* note 105, at 252.

111. Erwin Deutsch, *Medical Experimentation: International Rules and Practice*, 19 VICTORIA U. WELLINGTON L. REV. 1, 4 (1989). But see G.J. Annas, *The Changing Landscape of Human Experimentation: Nuremberg, Helsinki, and Beyond*, 2 HEALTH MATRIX 119-40 (1992) (arguing that the Nuremberg Code has achieved binding status similar to that of a treaty).

112. INTERNATIONAL SUMMIT CONFERENCE ON BIOETHICS, TOWARDS AN INTERNATIONAL ETHIC FOR RESEARCH WITH HUMAN BEINGS 39 (1987) [hereinafter CONFERENCE ON BIOETHICS]; see Michael A. Grodin et al., *Medicine and Human Rights: A Proposal for International Action*, HASTINGS CENTER REP., July-Aug. 1993, at 8 (noting that the Nuremberg Code "has been widely recognized, if not always followed by the world community").

113. Bassiouni et al., *supra* note 18, at 1611.

114. David N. Weisstub et al., *Establishing the Boundaries of Ethically Permissible Research with Vulnerable Populations*, in RESEARCH ON HUMAN SUBJECTS: ETHICS, LAW AND SOCIAL POLICY 355-56 (David N. Weisstub ed., 1998) [hereinafter RESEARCH ON HUMAN SUBJECTS]; see also 1975 Declaration of Helsinki, *supra* note 35, § I-11. "The draft version [of the Helsinki Declaration] also would not allow those children in institutions who were not under the care of relatives or those persons residing in mental hospitals or in hospitals for mental defectives to be subjects of human

laration of Helsinki further clouded the sweeping prohibitions of the Nuremberg Code by distinguishing between "non-therapeutic clinical research" and "clinical research combined with professional care." This distinction effectively created a loophole, by which researchers in Africa could perform human experimentation without the informed consent of their subjects simply by labeling their experiments "therapeutic."<sup>115</sup> Moreover, the ethical guidelines embodied in the Helsinki Declaration lack enforceability and therefore represent a step backward from the unequivocal prohibitions of the Nuremberg Code.<sup>116</sup>

Although the CIOMS Guidelines were drafted specifically to assist developing countries, they provide a more flexible approach to informed consent to accommodate communally-oriented societies such as those found in parts of Africa.<sup>117</sup> An ironic consequence of this flexible approach has been the approval of the African short course AZT studies and the continued exploitation of developing countries.<sup>118</sup>

### C. *Disparate National Laws Fail to Prevent Foreign Exploitation*

National regulation of human experimentation differs dramatically between developed and developing, particularly African, nations. Many African nations lack any legislative protections for subjects of medical research.<sup>119</sup> To a large degree, this legislative vacuum is intentional. While governments of these nations are desperate to bring medical research to their dying populations,<sup>120</sup> their nations cannot afford such research without subsidies from multinational pharmaceutical corporations.<sup>121</sup> To court these pharmaceutical corporations, African nations vie to minimize regulation on the conduct of medical research. They fear that legislation, and resulting lawsuits, could have a chilling effect on beneficial research efforts.<sup>122</sup> As a result, African nations have shown great reluc-

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experimentation." Bassiouni et al., *supra* note 18, at 1645; see also World Medical Association, *Draft Code of Ethics on Human Experimentation*, 2 BRIT. MED. J. 1119 (1962).

115. See Robert J. Levine, *Clarifying the Concepts of Research Ethics*, HASTINGS CENTER REP., June 1979, at 21-22 (noting that placebo-controlled drug trials "cannot be defined as either therapeutic or nontherapeutic").

116. Contrary to the Declaration of Helsinki, the Nuremberg Code has been found to have legally enforceable prohibitions, upon which civil actions may be brought in U.S. courts. See, e.g., *In re Cincinnati Radiation Litigation*, 874 F. Supp. 796, 821 (S.D. Ohio 1995).

117. Sharon Perley et al., *The Nuremberg Code: An International Overview*, in ANNAS & GRODIN, *supra* note 12, at 163.

118. Leonard H. Glantz et al., *Research in Developing Countries: Taking "Benefit" Seriously*, HASTINGS CENTER REP., Nov.-Dec. 1998, at 38-39 (recognizing that the CIOMS Guidelines were "not strong or specific enough to prevent exploitation").

119. CONFERENCE ON BIOETHICS, *supra* note 112, at 39. Further, these developing countries lack a developed tort law system. See generally Jonathan Todres, *Can Research Subjects of Clinical Trials in Developing Countries Sue Physician-Investigators for Human Rights Violations?*, 16 N.Y.L. SCH. J. HUM. RTS. 737 (2000) (arguing in favor of a cause of action in U.S. courts for African subjects injured as a result of their participation in U.S. research).

120. See Olson, *supra* note 19, at A3.

121. Dawn Joyce Miller, Comment, *Research and Accountability: The Need for Uniform Regulation of International Pharmaceutical Drug Testing*, 13 PACE INT'L L. REV. 197, 212-13 (2001).

122. Todres, *supra* note 119, at 767.

tance to impose any restrictions on human research, thereby creating a medical "race to the bottom" at the expense of human rights and human life.<sup>123</sup>

For example, although the Ivory Coast submits all human research protocols to a "Research Committee" for review and approval, the government lacks any "special requirements for obtaining informed consent from the human subjects."<sup>124</sup> Even where these ethical review boards review research protocols, corruption often prevents these boards from protecting the interests of experimental subjects.<sup>125</sup> While this corporate-friendly environment benefits transnational corporations, it does so to the detriment of African citizens. This lack of effective regulation has given a perverse incentive to scientists in developed countries to conduct human trials in Africa when they cannot get approval for such research at home.<sup>126</sup>

#### *D. International Law on Informed Consent Lacks Substance and Enforcement*

Current international human rights treaties are not sufficient to prevent physicians and scientists from experimenting on subjects without their voluntary consent.<sup>127</sup> Although several treaties give lip service to the right of informed consent, there exists no specific treaty obligation that adequately protects research subjects from nonconsensual experimentation. The Universal Declaration of Human Rights (UDHR), while establishing the concept of "bodily

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123. King, *supra* note 8, at 202 (arguing that "differences in ethical standards between the host and sponsoring communities . . . can actually undermine the regulation of human experimentation by creating an incentive for countries to underregulate or underenforce scientific research, including research involving human subjects").

124. Richard J. Kelly et al., *The Regulation of Research on Human Subjects: A Decade of Progress*, in *ETHICS AND RESEARCH ON HUMAN SUBJECTS*, *supra* note 77, at 137-38; *see also id.* at 138 (noting that Malawi, the United Republic of Tanzania, Zaire, and Zambia have no legal procedures for obtaining informed consent). *But cf.* CLINICAL TRIALS IN DEVELOPING COUNTRIES, *supra* note 3, at 44 (noting that Uganda prohibits reliance solely on the permission of a community leader (citing S. Loue, Testimony Before NBAC, Oct. 21, 1999)); Kelly et al., *supra*, at 139 (noting that Zimbabwe requires that "the voluntary written consents of all such persons taking part in the clinical trial have been freely obtained").

125. Bayer, *supra* note 29, at 569.

Researchers in developing countries are from higher social classes than those who are research subjects, and, thus, those researchers are unlikely to safeguard their subjects' interests. The lure of collaboration might simply overcome ethical scruples, given the "obvious benefits in prestige and, perhaps, in salary."

*Id.* (quoting Letter from Peter Lurie et al. to Donna Shalala, *supra* note 31).

126. Peter Lurie et al., *Ethical, Behavioral, and Social Aspects of HIV Vaccine Trials in Developing Countries*, 271 JAMA 295, 296 (1994). Pursuant to U.S. law, government research in foreign countries may be conducted where the foreign country provides "equivalent protection of human subjects." 45 C.F.R. § 46.101(h). The ambiguous meaning of "equivalent protection" has led to the approval of research abroad that clearly would not be permitted in the United States. *See* Dickens, *supra* note 66, at A-9 ("The protection of human subjects [in 45 C.F.R. § 46] is therefore less a goal in itself than a necessary means or condition of promoting medical research designed to protect the long-term health of populations, some of whose members will be invited to take the risks of becoming its short-term subjects.").

127. George J. Annas & Michael A. Grodin, *Medical Ethics and Human Rights: Legacies of Nuremberg*, 3 HOFSTRA L. & POL'Y SYMP. 111, 121 (1999).

integrity,"<sup>128</sup> lacks the specificity necessary to provide a link to human experimentation.<sup>129</sup> The International Covenant on Civil and Political Rights (ICCPR), which was intended to create enforceable rights from the UDHR, specifically states that "no one shall be subjected without his free consent to medical or scientific experimentation."<sup>130</sup> Despite this clear adoption of the doctrine of informed consent, the ICCPR "is hobbled by weak implementation provisions."<sup>131</sup> The provisions for international implementation of the ICCPR provide for the creation of a Human Rights Committee.<sup>132</sup> The Committee is structured to deal with reports from interested parties and to consider complaints by one state that another has not fulfilled its obligations. This procedure, while theoretically advantageous, has been criticized as highly complicated, ineffective in inciting change, and subject to long delays.<sup>133</sup> After over three decades in existence, the Committee has yet to review a single case of medical experimentation.<sup>134</sup>

Regional agreements, such as the CHRB, demonstrate the lack of shared values and differences in legal systems among nations.<sup>135</sup> In addition, despite the relative comprehensiveness of the CHRB's protections, its prohibitions do not apply extraterritorially.<sup>136</sup> As a result, the CHRB's "international" legal regulation of human experimentation nevertheless fails to provide any protection for subjects of research conducted by European corporations in developing countries.

Without effective multilateral treaties, there can be no customary international law regulating informed consent to human experimentation.<sup>137</sup> Custom-

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128. Universal Declaration of Human Rights, G.A. Res. 217, U.N. GAOR, 3d Sess., Supp. No. 51, at 3, U.N. Doc. A/810 (1948).

129. Bassiouni et al., *supra* note 18, at 1656.

130. International Covenant on Civil and Political Rights, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316, reprinted in 6 I.L.M. 368 (1967) [hereinafter ICCPR]. Specifically, article 7 of the ICCPR provides in full that "[n]o one shall be subjected to torture or to cruel, inhuman, or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." *Id.* at art. 7. Professor David Fidler has argued that involuntary medical experimentation may also implicate the ICCPR's protections of the right to life and the right not to be subjected to degrading treatment. David P. Fidler, "Geographical Morality" Revisited: *International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries*, 42 HARV. INT'L L.J. 299, 328-37, 343-44 (2001).

131. Bassiouni et al., *supra* note 18, at 1657.

132. Optional Protocol to the International Covenant on Civil and Political Rights, G.A. Res. 2200A, U.N. GAOR, 21st Sess., Supp. No. 16, at 59, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 302.

133. Bassiouni et al., *supra* note 18, at 1657 n.294.

134. Fidler, *supra* note 130, at 338.

135. Bassiouni et al., *supra* note 18, at 1659 (citing Lopez-Rey, *Crime and Human Rights*, 42 FED. PROB. 10, 12 (1978)); cf. Povl Riis, *Perspectives on the Fifth Revision of the Declaration of Helsinki*, 284 JAMA 3045, 3046 (2000) (noting that the CHRB is "expected to exert a strong influence on research ethics outside Europe").

136. Trigilio, *supra* note 86, at 660; Giles Tremlett, *European Nations Sign Ban on Human Cloning*, TIMES (LONDON), Apr. 5, 1997, at 18 (criticizing that "European biomedical companies could easily get around the [CHRB's] restrictions by carrying out experiments in Third World countries without legislation to control research").

137. See Anthony D'Amato, *Human Rights as Part of Customary International Law: A Plea for Change of Paradigms*, 25 GA. J. INT'L & COMP. L. 47, 96 (1996) (noting that because widely ac-

ary international law, derived from the “general and consistent practice of states followed by them from a sense of legal obligation,”<sup>138</sup> binds a nation regardless of whether or not it has bound itself by treaty.<sup>139</sup> Although some commentators argue that the right of free and informed consent is already a norm of customary international law,<sup>140</sup> there is neither widespread nor consistent state practice supporting such a right.<sup>141</sup> Such widespread, consistent state practice protecting the right of informed consent can be achieved only through defined rules—rules laid out in a multilateral treaty.

## VI. PROPOSED REGULATION

No single international legal standard guides physicians in obtaining the consent of their subjects.<sup>142</sup> Rather, human experimentation is guided only by a host of informal guidelines, and individual nations lack the capacity to punish physicians for human experimentation in violation of those guidelines.<sup>143</sup> The diversity of these modern guidelines creates problems in the regulation of international experimentation, where physicians from developed countries simply capitalize on those developing countries adhering to the least protective informal guidelines.<sup>144</sup>

Current prohibitions on human experimentation do not solidify the absolute nature of the right of free and informed consent. Physicians and scientists need the support of an absolute international standard to uphold basic medical ethics and hold accountable those who violate such ethics.<sup>145</sup> Without an international

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cepted multilateral treaties create legal obligations incorporating consistent state practice, “provisions in treaties transmute into norms of customary law”); *see also* Continental Shelf (Libya/Malta), 1985 I.C.J. REP. 29 (June 3) (finding that multilateral conventions “may have an important role to play in recording and defining rules deriving from custom, or indeed in developing them”).

138. RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 102(2) (1987).

139. *See* SIR ROBERT JENNINGS & SIR ARTHUR WATTS, *OPPENHEIM’S INTERNATIONAL LAW* 27-29 (9th ed. 1992).

140. *E.g.*, DAVID FIDLER, *INTERNATIONAL LAW AND INFECTIOUS DISEASES* 258 (1999); Dickens, *supra* note 66, at A-8 (noting that “the principle that each individual proposed to be at personal risk in a study should be able to give, or effectively deny, consent” is an *erga omnes* norm, binding all nations).

141. The African short course AZT testing is but another example reaffirming the lack of consistent state practice protecting a subject’s right to informed consent. *See* Bassiouni et al., *supra* note 18, at 1662 (“[A]sserting the need for a convention may also imply that the essential elements of customary law . . . may be lacking.”). *But cf.* Grodin et al., *supra* note 112, at 8 (stating that there is “universal condemnation of physicians who engage in . . . involuntary human experimentation under government auspices”).

142. *Supra* notes 129-129 and accompanying text.

143. ANNAS, *supra* note 105, at 252-53 (noting that neither punishment nor compensation is possible “because such experimentation is often justified on the basis of national security or military necessity”).

144. Bernard Starkman, *Models for Regulating Research: The Council of Europe and International Trends*, in RESEARCH ON HUMAN SUBJECTS, *supra* note 114, at 264, 268-69; *supra* note 123 and accompanying text.

145. *Cf.* ANNAS, *supra* note 105, at 256 (noting that human rights law is “necessary, but not sufficient, to prevent human rights abuses by physicians”).



standard, scientists may travel the globe in search of the subject with the least recognized rights. International prohibitions are crucial to punishing the abuses that cannot be punished by the country in which the physician works.

If such research would be impermissible in developed countries,<sup>146</sup> conducting this same research legally in the developing world is merely a form of medical exploitation. The short course AZT trials in Africa are the paradigmatic example highlighting the need for international regulation. In Africa, the failure of an international standard for informed consent permitted U.S. scientists to perform highly unethical experiments on African subjects with impunity. This cannot be allowed to happen again.

This Part proposes an international standard for guaranteeing the informed consent of human subjects, addresses the possibility of derogating from this standard to accommodate national health crises or promote cultural relativism, and recommends international mechanisms for implementing the right of informed consent. An international standard is both necessary and feasible. Although countries differ in their implementation procedures, there is wide transcultural acceptance of the general principles governing informed consent.<sup>147</sup> Furthermore, international law could secure greater subject protections over current ethical safeguards, alleviating the problems inherent in the current regulatory environment.<sup>148</sup>

The Nuremberg Code represents the strongest protection of the right of informed consent. Subsequent standards have detrimentally weakened this absolute requirement.<sup>149</sup> These weak subject protections must be removed, and they must be replaced by an absolute standard similar to that of the Nuremberg Code. This standard should apply to all subjects, regardless of whether the research could be construed as therapeutic or non-therapeutic. In addition to the core requirement of informed consent, it is vital to retain certain additional protections that have developed since the Nuremberg Code, such as peer review requirements and added protections for vulnerable populations. Such protections only provide further guarantees that physicians will respect all subjects' central right of free and informed consent.

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146. No scholar has yet made a compelling argument that informed consent should be abandoned in developed countries.

147. Domínguez-Urban, *supra* note 12, at 277.

148. *Supra* notes 102-102 and accompanying text.

149. *Supra* notes 65-99 and accompanying text.

## A. Regulatory Requirements

### 1. *Therapeutic v. Non-therapeutic*<sup>150</sup>

It is not always apparent whether research is therapeutic or non-therapeutic in nature.<sup>151</sup> This is particularly true in the case of AIDS and other life-threatening diseases.<sup>152</sup> As Professor George Annas notes:

Perhaps the major source of controversy surrounding drug trials for experimental AIDS drugs is that investigators see these trials as *research*, whose purpose is to provide generalizable knowledge that may help others. On the other hand, most individuals suffering with AIDS see these trials as *therapy*, whose primary purpose is to benefit them.<sup>153</sup>

Because of the life-threatening nature of the disease, the desperate subject may feel that he or she has “nothing to lose,” believing that participation in research may be the best hope for treatment.<sup>154</sup> “In the absence of health care, virtually any offer of medical assistance (even in the guise of research) will be accepted as ‘better than nothing’ and research will almost inevitably be confused with treatment . . . .”<sup>155</sup> Thus, for HIV positive subjects, “the distinction between treatment and experimentation has become blurred.”<sup>156</sup>

Yet, the consequences of labeling an experiment therapeutic or non-therapeutic are far reaching.<sup>157</sup> Although the distinction is not clear, physicians can artificially create less stringent informed consent requirements simply by labeling an activity “therapeutic.”<sup>158</sup> This “therapeutic illusion”<sup>159</sup> permits physi-

150. For the purposes of these recommendations, therapeutic and non-therapeutic may be referred to as clinical and experimental, respectively.

151. Weisstub et al., *supra* note 114, at 359 (quoting M.A. Somerville, *Therapeutic and Non-Therapeutic Medical Procedures — What Are the Distinctions?*, 2 *HEALTH LAW IN CANADA* 85, 88-89 (1981) (“[A] planned cause-effect study in which the action of a particular maneuver is contrasted with the results of a comparative, or control, maneuver, more often than not, falls on a spectrum between ‘pure therapy,’ at one end, and ‘pure research’ on the other.”)). For a variety of definitions of therapeutic and non-therapeutic, see ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 3 (1986).

152. King, *supra* note 8, at 10 (noting that the “confusion between research and treatment” undermines regulation of research aimed at treating AIDS); Morin, *supra* note 60, at 166.

153. ANNAS, *supra* note 11, at 133 (emphasis in original).

154. *Id.* at 135. Even the CIOMS Guidelines acknowledge that “[s]omeone without access to medical care may be unduly influenced to participate in research simply to receive such care.” CIOMS Guidelines, *supra* note 77, Guideline 19.

155. George J. Annas & Michael A. Grodin, *Human Rights and Maternal-Fetal HIV Transmission Prevention Trials in Africa*, 88 *AM. J. PUB. HEALTH* 560, 562 (1998) (noting that informed consent’s “protective power is much more compromised in impoverished populations who are being offered what looks like medical care that is otherwise unavailable to them”).

156. Wendy K. Mariner, *AIDS Research and the Nuremberg Code*, in ANNAS & GRODIN, *supra* note 12, at 291.

157. The categorization is important because less stringent rights protections exist for clinical research. See Levine, *supra* note 115, at 23. Since non-therapeutic research does not benefit the subject, those who regulate physicians consider it more ethically suspect and require more stringent safeguard mechanisms. *Id.* The differential standards for informed consent based upon this research-therapy distinction were first created in the Helsinki Declaration, which bypassed the need for informed consent in “clinical research.” *Supra* notes 72-74 and accompanying text.

158. See Jay Katz, *The Regulation of Human Experimentation—A Personal Odyssey*, 9 *IRB: A REVIEW OF HUMAN SUBJECTS RESEARCH* 1, 5 (1987) (noting that “the establishment of [U.S.] regulations for the conduct of human research has led investigators both wittingly and unwittingly to label

cians to use nonconsensual subjects under the superficial guise that the research would, in some undefined sense, benefit the subject or those with similar characteristics.

Applying a universal standard would protect the rights of the patient-subject during the course of treatment, research, and those—like the short course AZT trials—that fall into neither category. Removing the therapeutic/non-therapeutic distinction would be consistent with the substantive goals of the doctrine of informed consent: providing autonomy and self-determination to the subject.<sup>160</sup> Subjecting both types of research to the same regulations would also enhance the procedural goals of the doctrine of informed consent, mandating the disclosures essential to shared decision-making without exploitation. Further, such uniform regulation would not curtail a separate standard from being used for proven medical treatments, allowing public health measures such as mandatory vaccinations or nutritional supplements to continue.<sup>161</sup>

Separate standards governing informed consent based upon this research-therapy distinction should be abandoned. There is no plausible objective basis for distinguishing research from therapy.<sup>162</sup> As the short course AZT studies show, there may exist circumstances where the physician intends both to benefit the patient and to gain information about an innovative therapy.<sup>163</sup> In this paradigmatic case, reputed physicians have looked at the same facts and come to different conclusions about the therapeutic value of the short course trials.<sup>164</sup> Even if physicians could be held to an objective standard for therapeutic treatment—treatment designed *solely* to improve the physical state of the individual<sup>165</sup>—this would nevertheless involve a subjective component: whether the physician reasonably expects that the treatment will succeed.<sup>166</sup> Where there

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their interventions 'therapy' rather than 'research' in order to avoid the requirements of protocol review").

159. Jay Katz, *Human Sacrifice and Human Experimentation: Reflections at Nuremberg*, 22 YALE J. INT'L L. 401, 408 (1997) (citing ADVISORY COMM'N ON HUMAN RADIATION EXPERIMENTS: FINAL REPORT 143 (1995)).

160. *Supra* notes 10-10 and accompanying text; see, e.g., King, *supra* note 8, at 12 ("Researchers may offer patient-subjects participation in research, wrongly characterizing it as for their benefit; and when they participate in research, patient-subjects may also wrongly feel betrayed when they are treated as subjects rather than as patients.").

161. See Delgado & Leskovic, *supra* note 14, at 67 (noting that "[t]here is almost universal agreement that the requirement of informed consent should be applied more rigorously in connection with experimental procedures, or 'research,' than with standard medical or psychological treatments").

162. R. Gillon, *Ethical Review Procedures: A Developed Country's Perspective*, in ETHICS AND RESEARCH ON HUMAN SUBJECTS, *supra* note 77, at 81 ("I know of no way of quantifying the balance between therapeutic and non-therapeutic intent."). Further, subjects in developing countries often cannot distinguish between treatment and research. CLINICAL TRIALS IN DEVELOPING COUNTRIES, *supra* note 3, at 48 (recommending that researchers attempt to minimize this "therapeutic misconception").

163. Nancy M.P. King, *Experimental Treatment: Oxymoron or Aspiration*, HASTINGS CENTER REP., July-Aug. 1995, at 6, 9 (noting the use of the term "innovative therapy" as "an attempt to sidestep the research-treatment distinction").

164. *Supra* notes 29-31 and accompanying text.

165. See LEVINE, *supra* note 151, at 3.

166. King, *supra* note 163, at 9 ("[W]hat about treatments that are intended to benefit the patient, when there are questions about the reasonableness of the expectation of success?"). It is im-

can be no objective basis for distinguishing therapeutic from non-therapeutic research, abandoning this subjective distinction is the only way to have universally applicable protection of a subject's right of informed consent.

## 2. *Vulnerable Population—The African HIV Positive Subject*

The international community has consistently identified populations as "vulnerable" based upon their inherent incapacity to give truly free and informed consent.<sup>167</sup> Yet, there exists no consensus that experiments with certain of these vulnerable populations should be banned altogether,<sup>168</sup> and, as such, "international law provides no support for terminating clinical research . . . because of such vulnerability."<sup>169</sup>

Procedurally, there may be inherent limitations to informed consent "in the intellectual capacities, psychological forces, and social pressures operating in and on" the vulnerable research subject.<sup>170</sup> These factors may limit the autonomy of the poverty-stricken HIV positive subject in a developing nation. Autonomy can only be achieved if a decision is properly informed. "[U]nless the potential subject has the intellectual capacity and insight to comprehend fully the risks involved, consent merely represents innate confidence in the technical judgement [sic] of the investigator."<sup>171</sup> Without the understanding to make an autonomous decision, a subject remains "in a state of submission, admiration, obedience to the doctor."<sup>172</sup> As one scholar has noted, "[t]he presence of doctors in white coats in a therapeutic setting among patients may result in the misplaced notion that what is being done is for a patient's own good."<sup>173</sup>

Substantively, populations subjected to medical experimentation can be vulnerable due simply to their dire need for health care, nutrition, and money.<sup>174</sup> This need for care makes them vulnerable because it makes them inherently

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possible to make expectation of success an objective assessment because "[u]ncertainty is inherent in therapeutic practice." LEVINE, *supra* note 151, at 3.

167. CIOMS Guidelines, *supra* note 77, Guideline 11; see Weisstub et al., *supra* note 114, at 357 (suggesting that vulnerability leads to "an inability to protect oneself from exposure to an unreasonable risk of harm"); cf. *id.* at 358 (noting that "adults should be presumed to be competent and capable of providing valid consent, unless the opposite is found to be the case"). But see McDonnell, *supra* note 98, at 1 (arguing that "care-givers are competent to involve themselves and their dependents in scientific work").

168. Weisstub et al., *supra* note 114, at 356.

169. Fidler, *supra* note 130, at 341.

170. KATZ, *supra* note 1, at 609.

171. Bankowski et al., *supra* note 78, at 229; see also Kass & Hyder, *supra* note 38, at B-27 ("It is not possible to claim a person who has never heard of a bacteria or virus is informed about what a vaccine or drug is doing or how their participation fits into any such study." (quoting an anonymous researcher)).

172. Anna Freud, *Unpublished Manuscript, Based on a Lecture to Students at Western Reserve Medical School* (Oct. 29, 1964), reprinted in KATZ, *supra* note 1, at 635. This unquestioning obedience is prevalent in Africa, where subjects "are unused to questioning a doctor's wisdom." Nowak, *supra* note 27, at 1334.

173. Dominguez-Urban, *supra* note 12, at 271 (citation omitted); cf. Todres, *supra* note 119, at 767 n.98 (finding "that villagers [in Thailand] rarely distinguish between the physician-as-researcher and the physician-as-caretaker").

174. Glantz et al., *supra* note 118, at 38-39; Fidler, *supra* note 130, at 339 ("[T]he consent of pregnant African women infected with HIV to participate in the clinical trials was not freely given in

unable to protect their own interests.<sup>175</sup> In developing countries, HIV positive subjects may be particularly vulnerable to nonconsensual experimentation because of their lack of political power, lack of education, unfamiliarity with medical interventions, and extreme poverty.<sup>176</sup> This is especially true for the specific sub-populations suffering—mostly women, children, and the indigent—who may be coerced into experiments due to their status and societal powerlessness.

African societies place obligations on HIV positive patients to cooperate with health professionals.<sup>177</sup> The very nature of the physician-subject relationship in such circumstances adds elements of coercion.<sup>178</sup>

Incapacitated and hospitalized because of illness, frightened by strange and impersonal routines, and fearful for his health and perhaps life, he is far from exercising a free power of choice when the person to whom he anchors all his hopes asks, "say, you wouldn't mind, would you, if you joined some of the other patients on the floor and helped us to carry out some very important research we are doing?"<sup>179</sup>

Studies have confirmed that even when African subjects have received sufficient information, their consent nevertheless may not be voluntary.<sup>180</sup>

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a substantive rather than procedural sense because of the desperate health situation these women faced.").

175. LEVINE, *supra* note 151, at 77 (noting that the judgments of diseased subjects "may differ drastically from those the same individuals would make when not suffering"); see also B.O. Osuntokun, *Individual Consent: A Perspective of Developing Countries*, in ETHICS AND RESEARCH ON HUMAN SUBJECTS, *supra* note 77, at 25 ("Those whose autonomy is diminished or who are vulnerable in other ways may be unable to protect their interest to the same extent and level that autonomous people can."); MARTHA ALBERTSON FINEMAN, *THE NEUTERED MOTHER, THE SEXUAL FAMILY AND OTHER TWENTIETH CENTURY TRAGEDIES* 190 (1995) (noting, in the context of paying indigent American mothers to use Norplant as birth control, that "[w]hen confronted with an economic 'incentive,' the notion she has a 'choice' in such circumstances seems illusory").

176. Glantz et al., *supra* note 118, at 38-39; Fidler, *supra* note 130, at 338 (citing Todres, *supra* note 119, at 757) ("[M]edical and scientific researchers have confronted problems in obtaining 'free consent' in developing countries because the low level of education among research subjects makes it difficult to determine whether a person fully understands to what he or she is giving consent.").

177. See LEVINE, *supra* note 151, at 76 (explaining that the "social definition of illness imposes upon the responsible sick person the obligation to seek and cooperate with competent help (ordinarily health professionals); if he or she fails in these responsibilities, his or her sick role will eventually come to be seen as illegitimate (irresponsible)").

178. There is agreement that coercion consists of:

any action, or threat of action, which compels the patient to behave in a manner inconsistent with his own wishes. The compelling aspect can be direct physical or chemical restraint, or it can be indirect threatened recriminations or indirect "force of authority" which convinces the patient that no other legal or medical alternative is available to him.

Peter Breggin, *Coercion of Voluntary Patients in an Open Hospital*, 10 ARCHIVES GEN. PSYCHIATRY 173, 173 (1964). Populations who historically have been coerced into participating in human experimentation include "(1) imprisoned convicts, (2) inmates of mental hospitals or domiciliary institutions, (3) patients in 'free' or 'clinic' hospitals, often affiliated with medical, educational, or research facilities, (4) indigent patients, (5) service men, and (6) children, including the mentally handicapped and (7) fetuses." Bassiouni et al., *supra* note 18, at 1613.

179. Franz J. Ingelfinger, *Informed (But Uneducated) Consent*, 287 NEW ENG. J. MED. 466, 466 (1972).

180. Quarraisha Abdool Karim et al., *Informed Consent for HIV Testing in a South African Hospital: Is It Truly Informed and Truly Voluntary?*, 8 AM. J. PUB. HEALTH 637, 638-39 (1990) (noting the results of a South African study, in which 93% of subjects for HIV testing who were

Yet it cannot be denied that experimentation with diseased subjects has great scientific value. It is their disease that makes them the "most used and useful of all experimental subjects."<sup>181</sup> In addition, experimentation should continue to be done in developing countries if the benefits of such experimentation are to be applied in these countries. As one author notes,

a drug that is regarded as safe and effective in a developed country cannot be presumed to be equally beneficent in a developing country that "lacks ancillary medical, nutritional, and distributional services." Thus, failing to test a drug prior to marketing represents merely a shift to post-marketing experimentation and raises human rights issues of its own.<sup>182</sup>

However, there should be concern that "[s]uch individuals thus become experimental subjects mainly because of convenience and not necessarily because the experiment is meritorious."<sup>183</sup>

Because these experiments must continue in developing countries, special protections are necessary to protect these diseased subjects. Due to their vulnerable status, "no matter how much explanation is given, or in which way, explanations of risk are not accepted the same way by everybody."<sup>184</sup> Therefore, rather than looking to an objective standard for coercion, whether or not a subject has signed a consent form, the focus should be on a subject's subjective feelings or responses.<sup>185</sup> Where research protocols themselves do not specify anything beyond an objective test for informed consent (with simply a signature evidencing a subject's consent), physicians should be expected to tailor their explanations of research and its risks in light of the danger of the experiment and the vulnerability of the individual subject.

This could be accomplished through interviews with the potential subjects by host country physicians, both before and after the signing of consent forms. It should not merely be the signing of a form, but an agreement between informed individuals. Potential subjects should be able to explain to what they have given their consent. Only through genuine interaction will experimentation with inherently vulnerable subjects not be viewed as exploitation of those unable to defend themselves.

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repeatedly told that testing was voluntary still felt compelled to be tested); *Is Informed Consent Voluntary?*, 279 JAMA 1429, 1429 (1998).

181. Ingelfinger, *supra* note 179, at 466.

182. Dominguez-Urban, *supra* note 12, at 275 (citation omitted); *see also* Miller, *supra* note 121, at 223 ("Strains of AIDS common in developed nations often differ from those present in developing African nations. Yet, the vaccines tested in these developing nations are generally intended to produce treatments for the strains of disease present in developed nations." (citations omitted)).

183. Bassiouni et al., *supra* note 18, at 1614 (citing Appel, *Ethical and Legal Questions Posed by Recent Advances in Medicine*, 203 JAMA 513 (1968)).

184. Weisstub et al., *supra* note 114, at 370.

185. *See* Breggin, *supra* note 178, at 173. *But cf.* Fidler, *supra* note 130, at 338 ("Analysis of the right of free consent in the clinical trial context cannot have as its objective the determination that the person in question really gave full, informed, and free consent.").

### 3. Enforcement—Peer Review

An enforcement system is necessary if international regulation is to have any meaning.<sup>186</sup> Criminal and civil penalties may punish physicians and compensate subjects, but peer review of research protocols by an ethical review committee can prevent violations of subjects' rights before they happen. Although not initially part of the Nuremberg Code, peer review has become an effective means of monitoring the acts of physicians.<sup>187</sup>

The lack of a clear peer review system in international regulation of human experimentation is the result of the erroneous "belief that a responsible, ethical and informed investigator is the one on whom the ultimate responsibility for the conduct of the experiment and the welfare of the subject lies."<sup>188</sup> Yet, the physician and subject often have competing goals in the research.<sup>189</sup> Because a subject may be willing to submit to unethical experimentation, additional safeguards are necessary when a subject's consent may not truly be informed or voluntary.<sup>190</sup>

Peer review should confirm that research protocols are safe. In addition, the reviewers must be able to act when protocols threaten a subject's rights. Although the Helsinki Declaration and CIOMS Guidelines were giant steps forward in providing legal and ethical transparency of protocols, the committees created under them do not have the authority to approve or reject research protocols based upon insufficient informed consent protections.<sup>191</sup> Where research protocols do not adequately ensure the informed consent of research subjects, peer review committees must have the responsibility and the authority to reject the research.<sup>192</sup> To accomplish this, research protocols should be submitted to peer review systems and approved prior to any contact with potential subjects. These peer review systems should consist of well-funded committees, free from political and monetary influence, composed of members from a wide range of disciplines, specifically created to consider the ethics and legality of a research protocol, and having the authority to recommend modifications to the proposed research, to reject the protocol outright, or to approve the research.<sup>193</sup>

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186. See Dominguez-Urban, *supra* note 12, at 276.

187. Peer review was developed in the United States in the 1960's and soon thereafter was adopted by several other developed countries. P.M. McNEILL, *THE ETHICS AND POLITICS OF HUMAN EXPERIMENTATION* 37-50 (1993). As a result of its widespread acceptance, peer review was incorporated into the CIOMS Guidelines. See *supra* note 79 and accompanying text.

188. Bassiouni et al., *supra* note 18, at 1651.

189. *Supra* notes 11-15 and accompanying text.

190. See Perley et al., *supra* note 117, at 162 (noting that subjects "may not be sufficiently aware of the implications of participating in an experiment to give adequately informed consent").

191. See 1989 Declaration of Helsinki, *supra* note 65, § I(2) (endowing committees with the authority to provide "consideration, comment and guidance").

192. See Bassiouni et al., *supra* note 18, at 1652.

193. See Paul M. McNeill, *International Trends in Research Regulation: Science as Negotiation*, in *RESEARCH ON HUMAN SUBJECTS*, *supra* note 114, at 244; see also King, *supra* note 8, at 189 n.130 (noting the importance of having lay persons on committees as a means of preventing the committees from simply becoming another method of physician self-regulation). Some of these recommendations derive from factors identified by the U.S. Office of Technology Assessment as essential for the makeup of successful biomedical ethics bodies in the United States. See OFFICE OF

These peer review systems are of particular importance in Africa.<sup>194</sup> Experience has shown that well-structured ethical review boards can be effective in Africa to reign in researchers who act in violation of informed consent procedures.<sup>195</sup> Although Africa was slow to establish peer review committees, known as institutional review boards, AIDS has changed the degree to which Africans review research.<sup>196</sup> Effective ethical review boards in both the home and the host countries would assure that peer review continues to protect the subjects' right of informed consent.

*B. Derogation—Is Informed Consent Culturally Relative?*<sup>197</sup>

*1. Utilitarian/Communitarian Justifications*

American proponents of U.S. testing and African physicians struggling to find a cure for the AIDS pandemic on their continent have made similar arguments for the legal and ethical propriety of the short course AZT trials. First, they asserted a utilitarian argument that the individual African subject's right of informed consent can be derogated in order to find a cure for all of society. Second, they argued that the right to informed consent is a uniquely Western concept, entirely foreign when applied in Africa. Taken together, these arguments reflect "a communal-oriented approach regarding the ethical appropriateness of the tests"<sup>198</sup> that directly conflicts with the doctrine of informed consent.

*a. Derogation in Time of Emergency*

Because the AIDS pandemic has largely become "a disease of poverty rather than wealth," consideration of economic, social, and cultural rights raises questions of resource allocation and economic justice.<sup>199</sup> The International Covenant on Economic, Social, and Cultural Rights guarantees the right of everyone to enjoy health and the benefits of scientific progress.<sup>200</sup> Proponents of the short course AZT testing in Africa argued that the right to health for all

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TECHNOLOGY ASSESSMENT, BIOMEDICAL ETHICS IN U.S. PUBLIC POLICY – BACKGROUND PAPER 18 (1993).

194. Nowak, *supra* note 27, at 1332. Peter Piot, head of the United Nations Program on HIV/AIDS, commented that "the major issue is to have independent committees in every country that does AIDS research . . ." *Id.*

195. *E.g., id.* (noting an episode in which an African ethical review board ousted a researcher for conducting unapproved sideline HIV research in addition to the research for which he had received his initial approval and funding).

196. *Id.* But cf. Letter from Peter Lurie et al. to Harold T. Shapiro (Dec. 6, 2000), <http://www.citizen.org/hrg/publications/1550.htm> (arguing that the institutional review boards in developing countries are "often grossly inadequate").

197. This is a legal equivalent to the ethical question posed by Dennis Cooley: "Is it morally permissible to lower testing standards for the Third World?" Dennis R. Cooley, *Second Best: A Case for Lowering Testing Standards in Third World Countries*, TWENTIETH WORLD CONGRESS OF PHILOSOPHY, Aug. 10-15, 1998, at 6, available at <http://www.bu.edu/wcp/Papers/Bioe/BioeCool.htm>.

198. Dyckman, *supra* note 34, at 107.

199. FIDLER, *supra* note 140, at 209.

200. International Covenant on Economic, Social, and Cultural Rights, 1966, art. 15(1)(b), reprinted in BASIC DOCUMENTS ON HUMAN RIGHTS 114 (3d ed., 1996) [hereinafter ICESCR].



individuals outweighs the right of a single individual subject to informed consent and other protections.<sup>201</sup>

A state has a fundamental obligation to provide for the health of its people.<sup>202</sup> Guaranteeing the right to health requires a state, at a minimum, "to protect the community from the further spread of [HIV/AIDS]."<sup>203</sup> Proponents argue that the survival, health, and safety of a population may outweigh the rights of an individual, and a state has an obligation to protect the health of its people where these interests outweigh those of the individual.<sup>204</sup> Pursuant to proponents' utilitarian reasoning, the rights of the individual are not absolute and may be restricted so long as the burdens on this right are necessary to achieve a compelling public health interest.<sup>205</sup> Proponents asserted that the AIDS epidemic in Africa is undoubtedly a compelling public health interest, and that restrictions of the right of free and informed consent were necessary to achieve that interest because these restrictions were proportional to the public health interest and were the least restrictive measure possible to achieve that interest.<sup>206</sup> They further argued, accepting that the burdens may outweigh the benefits of research in the short term, that "where it is a choice between either saving some from unnecessary pain or doing nothing, we should choose the former."<sup>207</sup>

African physicians, desperate for a solution to the AIDS pandemic,<sup>208</sup> argued that they could not afford to follow burdensome informed consent proce-

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201. Annas & Grodin, *supra* note 155, at 562.

202. Health is a fundamental human right implicit in the Universal Declaration on Human Rights. Specifically, the affirmative requirements under the International Covenant on Economic Social and Cultural Rights require a state to take positive steps to prevent serious risks to health. ICESCR, *supra* note 200, arts. 12, 15. There exists customary international law for a right to health, which has been interpreted to include—at a minimum—the prevention and treatment of major threats to public health. FIDLER, *supra* note 140, at 194 (noting that, "as suggested by analysis of treaties proclaiming the right to health, the right to health contains minimum core obligations centred [sic] on infectious disease control").

203. FIDLER, *supra* note 140, at 209.

204. An example of this is seen in the remarks of James Makumbe, the Ugandan Minister of Health, who announced that his country was "ready to provide subjects for HIV vaccine trials in return for health care services." Charles Henderson, *Uganda Will Provide Vaccine Subjects in Return for Services*, INFECTIOUS DISEASE WKLY., Mar. 4, 1996, at 1. These remarks show how willing countries may be to "barter" their citizens to science in exchange for societal benefits. See, Dyckman, *supra* note 34, at 106.

205. Levine, *supra* note 25, at 45.

A utilitarian calculation concludes that the most efficient study is the most ethically sound. . . . The sooner a trial is completed, the faster the new, affordable regimen (if proven effective) can be made available to pregnant women in the developing country.

*Id.*

206. L.O. GOSTIN & Z. LAZZARINI, HUMAN RIGHTS AND PUBLIC HEALTH IN THE AIDS PANDEMIC 103 (1997).

207. Cooley, *supra* note 197, at 3; see also *id.* at 4 (arguing that "NIH and CDC are merely choosing the lesser of two evil alternatives").

208. Olson, *supra* note 19; David D. Ho, *It's AIDS, Not Tuskegee: Inflammatory Comparisons Won't Save Lives*, TIME, Sept. 29, 1997, at 83 (noting that over 1000 newborns each day are born with the HIV virus).

dures in the face of widespread death.<sup>209</sup> The short course AZT trials were allegedly tailored specifically for Africa, to create lifesaving vaccines expeditiously while taking into consideration local needs and the constraints of African communities.<sup>210</sup> These physicians held that African nations did not have the resources to comply with individual protections.<sup>211</sup> Because AIDS has no known cure and there is no affordable treatment in Africa, proponents claimed that the best hope for African persons with AIDS was through experimental AIDS drugs.<sup>212</sup> U.S. proponents of the testing argued that testing needed to be done in Africa. They argued that because of poverty and lack of foreign subsidy, existing therapies were not available to African nations, making African subjects suffer from a unique problem that did not afflict people in developed countries.<sup>213</sup> In effect, the argument suggests that since there was no proven treatment available in Africa, anything was better than nothing. Therefore, the short course AZT testing would have been unethical if done in the United States only because proven regimens were already the standard treatment for all U.S. subjects.

#### b. *Cultural Relativism*

Proponents of the testing further argued that the doctrine of informed consent is based on uniquely Western notions of individual rights and autonomy.<sup>214</sup> As such, they held that the informed consent standards laid down in ethical codes are not universally valid.<sup>215</sup> Under a theory of cultural relativism, supporters of the research argued that African notions of community should take precedence for research taking place in Africa,<sup>216</sup> and thus informed consent is

209. Joseph Saba & Arthur Amann, *Drug Tests Offer Hope to Victims*, ARIZONA REPUBLIC, Sept. 23, 1997, at B7.

210. Ho, *supra* note 208, at 83 (noting that the trials "were created for Africans, by Africans, with the good of their people in mind and with their informed consent").

211. Cooley, *supra* note 197, at 6.

It is a mistake of the highest degree to assume that the moral standards of the rich should be forced upon the poor. People are dying in Africa, this is the immediate concern that must be addressed. Once this problem is rectified, there is adequate time to discuss the moral niceties that only those with sufficient resources can afford.

*Id.* Ho, *supra* note 208, at 83.

212. The author notes that scientists promoting the African short course trials made the same argument as those who once defended the Tuskegee study—that but for the subjects' participation, they would have received no treatment at all. See Marcia Angell, *The Ethics of Clinical Research in the Third World*, reprinted in REVERBY, *supra* note 31, at 578-79.

213. Harold Varmus & David Satcher, *Ethical Complexities of Conducting Research in Developing Countries*, 337 NEW ENG. J. MED. 1003, 1004 (1997).

214. See Gordon, *supra* note 15, at 1328. Elsy Gordon has identified the Western individualist tradition inherent in the informed consent doctrine: "[I]nformed consent emphasizes the right of the individual to make decisions concerning medical treatment . . . [and] envisions the active participation of the individual patient in medical treatment and decisions about treatment." *Id.*

215. R.J. Levine, *Informed Consent: Some Challenges to the Universal Validity of the Western Model*, in CIOMS, *ETHICS AND EPIDEMIOLOGY: INTERNATIONAL GUIDELINES* (Z. Bankowski et al. eds., 1991).

216. A *Growing Dichotomy: The Gap Between Therapeutic Haves and Have-Nots*, AIDS ALERT, Jan. 1, 1998, available at 1998 WL 9747452 ("What works in the United States, which values individual rights, may not work in developing countries where the community needs super-

not necessary in these communities.<sup>217</sup> As an extreme example, one commentator noted that "in many African countries, there is no concept of the individual beyond one's role in the community."<sup>218</sup>

African physicians asserted that "[l]ocal health experts, bioethicists and affected groups are best qualified to judge the risks and benefits of any medical research."<sup>219</sup> Therefore, they bitterly opposed the informed consent standard, arguing that Westernized notions of informed consent merely impose a form of "medical-ethical imperialism" on developing nations.<sup>220</sup> In addition, African physicians insisted that individual autonomy is best protected "not by protection against research risks but by ensuring freedom of choice and participation in research,"<sup>221</sup> allowing the subject "to decide how and by whom decisions of consequence to his or her life are made."<sup>222</sup> Under this rationale, African physicians argued that those with AIDS have a right to be research subjects, bound only by their own culture's notions of consent.

## 2. *Informed Consent Is Nonderogable*

Scientific progress must not eclipse individual rights. The right of subjects to be free from involuntary experimentation is an absolute human right, from which no derogation is permissible.<sup>223</sup> The AIDS crisis in Africa, resulting in the widespread violation of subjects' right of free and informed consent while producing little benefit, exemplifies why this must be the case. No matter what the state of crisis, scientists may not, in the shadows of utilitarianism, use subjects against their will—particularly when those subjects are acting with dimin-

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sede individual ones." (quoting Hoosen Coovadia)). For a general discussion of cultural relativism in informed consent, see Dyckman, *supra* note 34, at 103-12.

217. Gordon, *supra* note 15, at 1322 (arguing that "in some non-Western cultures, individuals expect and desire that others will make decisions about their medical care and that individuals do not want to receive information on which such decisions will ultimately be based").

218. *Trials of HIV Vaccine Planned for Developing Countries*, 303 *BRITISH MED. J.* 1219, 1219 (1991); see also Jeremy Sugarman et al., *International Perspectives on Protecting Human Research Subjects*, in *CLINICAL TRIALS IN DEVELOPING COUNTRIES II*, *supra* note 38, at E-1, E-6 ("In some settings, the notion of individual informed consent can seem inappropriate, because important decisions are often made in conjunction with families or are even left to communities.").

219. Saba & Amann, *supra* note 209, at B7 (emphasis added); see also Danstan Bagenda & Philippa Musoke-Mudido, *A Reaction: We're Trying to Help Our Sickest People, Not Exploit Them*, *WASH. POST*, Sept. 28, 1997, at C03 ("Those who can speak with credibility for AIDS patients in Africa are those who live among and know the people here or have some basic cross-cultural sensitivity. We are suspicious of those who claim to speak for our people, yet have never worked with them.").

220. Carel B. Ijsselmuiden & Ruth R. Faden, *Medical Research and the Principle of Respect for Persons in Non-Western Cultures*, in HAROLD Y. VANDERPOOL, *THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS: FACING THE 21ST CENTURY* 281, 284 (1996); Dominguez-Urban, *supra* note 12, at 280; Ho, *supra* note 208, at 83. Ironically, prior to the short course AZT testing, "ethical imperialism" was used to refer to instances where U.S. testing in Africa took place in violation of U.S. research ethics. M. Barry, *Ethical Considerations of Human Investigations in Developing Countries: The AIDS Dilemma*, 319 *NEW ENG. J. MED.* 1083, 1083 (1988).

221. Mariner, *supra* note 156, at 291.

222. Gordon, *supra* note 15, at 1328.

223. Fidler, *supra* note 130, at 339 ("Cutting the individual out of the consent procedure would not be acceptable under international human rights law.").

ished autonomy. Further, cultural relativists may not deny essential rights to these vulnerable individuals in the name of place or culture.

Derogation of the right of informed consent is never permissible. Although a state has a fundamental obligation to provide for the health of its people, such public health objectives cannot be used as a justification for violating the human rights of subjects of experimentation.<sup>224</sup> "The respect for human rights in human experimentation demands that we see persons as unique, as ends in themselves."<sup>225</sup>

The fundamental right of informed consent is a means of protecting the autonomy and dignity of the individual against infringement by the state.<sup>226</sup> International law, since its modern recreation at the end of World War II, has promoted human rights as a means of protecting such individual liberties against the interests of the state.<sup>227</sup> Such is the position of the Nuremberg Code, which provides that "the voluntary consent of the human subject is *absolutely* essential."<sup>228</sup> The Nuremberg Code clarified this by requiring that the subject "be so situated as to be able to exercise free power of choice without . . . [any] ulterior form of constraint or coercion and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."<sup>229</sup> Future codes that departed from this rule have weakened the human rights regime protecting subjects of human experimentation and have done so at the peril of the individual. The Helsinki Declaration first moved away from the Nuremberg Code's absolute nature of consent by permitting "clinical treatment" without the consent of the subject.<sup>230</sup> The CIOMS Guidelines went even farther by allowing consent in a "communally-oriented society" through a "trusted intermediary or community leader."<sup>231</sup> If scientists and physicians are to avoid repetition of the violations that occurred during the African AZT trials, this trend must be reversed in favor of the inviolability of the right of informed consent.

### 3. *Cultural Rationalization*

Although cultural relativists argue that ethics should be relative to time and culture,<sup>232</sup> informed consent, based upon core notions of self-determination, is a

224. COMMITTEE ON HUMAN GENETIC DIVERSITY, *EVALUATING HUMAN GENETIC DIVERSITY* 65 (1997).

225. Elie Wiesel, *Foreword*, in ANNAS & GRODIN, *supra* note 12, at ix; see also RONALD DWORKIN, *TAKING RIGHTS SERIOUSLY* 198 (1977) (arguing the Kantian dogma that it is unjust to treat an individual as less than a full member of the human community).

226. DWORKIN, *supra* note 225, at 199.

227. H.L.A. Hart, *Between Utility and Rights*, 79 COLUM. L. REV. 828, 829 (1979) ("The new faith is that the truth must lie not with a doctrine that takes the maximisation [sic] of aggregate or average general welfare for its goal, but with a doctrine of basic human rights, protecting specific basic liberties and interests of individuals. . .").

228. Nuremberg Code, *supra* note 33, at 2 (emphasis added).

229. *Id.*

230. *Supra* notes 72-73 and accompanying text.

231. CIOMS Guidelines, *supra* note 77, Guideline 15.

232. *Supra* notes 214-222 and accompanying text. This is similar to an objection raised by Dr. Sauter, defense counsel for two of the physicians in the Doctors' Trial:

universal human right from which cultural variation is not permitted.<sup>233</sup> Even if some cultural relativism is to be tolerated,<sup>234</sup> the testing at issue in Africa did not involve matters of cultural variation. In this case, cultural relativism became a smokescreen used by those who profited from the testing.<sup>235</sup> Rather than cultural relativism, this appears to be a form of "cultural rationalization,"<sup>236</sup> through which culture was used to rationalize an otherwise economic or political decision.

First, cultural relativism does not apply to vaccine testing because the testing has to do with the politics and economics of the drug market, not African culture.<sup>237</sup>

Standards of health care, defined in this context as access to life-saving drugs, are not cultural norms, but are products of a market that perpetuates inequities and the effects of colonialism. By invoking a relativist claim in this context, supporters of the tests risk conflating cultural tradition with pragmatic principles dictated by harsh economic realities.<sup>238</sup>

It appears more likely that, in light of the economic impact of AIDS on African communities, community leaders chose to sacrifice individual subjects for what they perceived to be the good of the community.<sup>239</sup> It was improper for propo-

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The question asked here is always what the opinion of the medical profession in America is. For us in this trial, in the evaluation of German defendants, that is not decisive. In my opinion the decisive question is for example, in 1942, when the altitude experiments were undertaken at Dachau, what the attitude of the medical profession in Germany was . . .

*Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Law 10, United States v. Karl Brandt et al.*, Oct. 1948 – Apr. 1949, Vol. II, p. 85.

233. See M. Angell, *Ethical Imperialism? Ethics in International Collaborative Clinical Research*, 319 *NEW ENG. J. MED.* 1081, 1082 (1988).

There must be a core of human rights that we would wish to see honoured universally, despite local variations in their superficial aspects . . . . The force of local custom or law cannot justify abuses of certain fundamental rights and the right of self-determination on which the doctrine of informed consent is based is one of them.

*Id.*; see also *CLINICAL TRIALS IN DEVELOPING COUNTRIES*, *supra* note 3, at 36 ("U.S. sponsors of research in developing countries should adhere to internationally agreed-upon ethical standards of voluntary informed consent for research, even in the face of cultural variation.").

234. Of course, informed consent processes should be sensitive to cultural variations where embracing such variation enhances comprehension and autonomy in decisionmaking. See Ijsselmuiden & Faden, *supra* note 220, at 285; see also *CLINICAL TRIALS IN DEVELOPING COUNTRIES*, *supra* note 3, at 35 (noting that "the United States could modify its informed consent regulations to adapt to various cultural circumstances in other countries without compromising the substantive ethical standard of informed consent"). Examples of such variation include, *inter alia*, varying informed consent procedures in the language, symbolism, and traditions employed.

235. Those who profited from the testing were not limited solely to those who received financial compensation. In the African short course AZT trials, political profits were seen in the public appearance of efforts to combat the HIV epidemic in Africa and the avoidance of international scrutiny of scientists and the pharmaceutical industry.

236. The author has coined the term "cultural rationalization" to describe those situations in which Westerners have chosen to exploit notions of cultural relativism as a pretext for their own economic or political gain.

237. Dyckman, *supra* note 34, at 104-12.

238. *Id.* at 109.

239. See Kass & Hyder, *supra* note 38, at B-28 ("Remember that those communities have internal hierarchies of sex and class, too, so that what is in the leader's best interests may not be in the individual man or woman's best interests." (quoting an anonymous researcher)).

nents of the AZT short course testing to espouse culture to further these economic and political ends.

Second, even if cultural norms of communitarianism are considered relevant to drug research, inasmuch as personhood in Africa is thought to differ so fundamentally from Western society as to make the basic rights of individuals in Africa incomparable to that of Western cultures, these cultural norms are not prevalent enough in Africa to warrant them overcoming the presumption of an individual subject's right of informed consent. Although often argued by proponents of the testing,<sup>240</sup> there is no evidence to suggest that subjects in any non-Western culture would prefer not to receive informed consent.<sup>241</sup> As one Nigerian physician notes, the relativist assertion "that 'person' as an individual does not exist in the local language of some Bantus, and that 'personhood' is defined by one's tribe, village or social group can be true only in respect of some small ethnic groups: it is not true of most parts of Black Africa."<sup>242</sup>

Third, it borders on preposterous to argue that the African testing is based on African cultural norms when the testing protocols were designed by American scientists, who lived in the United States, and who did not consult African physicians.<sup>243</sup> While culture certainly may "inform[ ] the perception of health and illness"<sup>244</sup> among the African subjects, this clearly was not a consideration in drafting the research protocol.

Lastly, the communitarian argument in favor of testing is premised entirely on African communities receiving a benefit from the testing. In fact, among testing supporters who agreed that international legal and ethical standards had been violated, the potential benefits were put forward as ends worthy of the unethical means employed.<sup>245</sup> Recent data, however, suggest that African nations, in spite of their role in the creation of AIDS drugs, will not benefit from these new treatments. Even with far reduced HIV treatment costs, "HIV drugs

240. Gordon, *supra* note 15, at 1322 (noting that "subjects may value decisionmaking processes that are less confrontational and defer more to physician discretion") (emphasis added); *supra* notes 219-220 and accompanying text.

241. Elysa Gordon has attempted to show two cases in which ethnicity has been a factor in medical decisionmaking. Gordon, *supra* note 15, at 1341-43. Putting aside the merits of her specific cases, these cases nevertheless do not apply to the experimental AZT research in Africa. In her chosen cases, the patients, who were receiving accepted medical treatments, explicitly waived their right to consent individually for their medical care. In doing so, they consented. Contrary to this, the African subjects in the short course trials had not explicitly consented to have their community leaders make decisions for them. U.S. researchers had taken that decision from them.

242. Osuntokun, *supra* note 175, at 29; see also Nowak, *supra* note 27, at 1335 ("We are moving more and more away from colonial times, and autonomy for individuals—including in Africa—is more and more respected." (quoting Peter Piot)); CLINICAL TRIALS IN DEVELOPING COUNTRIES, *supra* note 3, at 36 ("defenders of [cultural relativism] 'have relied on limited and often dated anthropologic literature that does not reflect the rapid cultural changes brought about by colonialism and independence, warfare, and urbanization'" (quoting C.B. Ijsselmuiden & R.R. Faden, *Research and Informed Consent in Africa—Another Look*, 326 NEW ENG. J. MED. 830, 833 (1992))).

243. Dyckman, *supra* note 34, at 107 (noting that "these experiments cannot be viewed as a product of Ugandan culture or somehow unknowable by Western critics because they are genuinely Western in nature").

244. Gordon, *supra* note 15, at 1323.

245. See Cooley, *supra* note 197, at 6.

remain far beyond the monthly minimum wage in much of [Africa].<sup>246</sup> International efforts to raise money for these drugs have fallen woefully short of their goals.<sup>247</sup> Assuming stable national health care funding and international aid, less than two percent of HIV-positive individuals in Africa will be able to receive these life-saving medications.<sup>248</sup>

Cultural relativism did not apply to the short course AZT trials in Africa, yet it was used to cloud the issues surrounding the subject's absolute right of informed consent. Autonomy, belonging to the individual alone, applies universally. This is especially important in the case of non-therapeutic research, in which researchers' goals blatantly conflict with those of their subjects.<sup>249</sup> No consent can take the place of that of the subject him or herself.<sup>250</sup> Solutions must place emphasis back on the subject alone.

### C. International Convention for the Protection of Informed Consent

A treaty-based solution would offer the best hope of unifying disparate national legislation and solidifying weak international ethics codes. International legal scholars have considered the following factors to gauge the need for an international convention:

[w]hether it is agreed that a particular problem exists that may be susceptible of solution through the creation of a new or the improvement of an existing legal regime; [and] what other law already exists or is being formulated in the field.<sup>251</sup>

In analyzing these factors, this Article has articulated the existence of the problem of involuntary medical experimentation in developing countries and the lack of regulations capable of resolving this dilemma. As shown by the U.S.

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246. *Id.*; *Macroeconomics and Health: Investing in Health for Economic Development*, REP. COMMISSION ON MACROECONOMICS & HEALTH (World Health Org., Geneva, Switz.), Dec. 20, 2001, at 86-88.

247. Kofi Annan, *No Letting Up on AIDS*, WASH. POST, Nov. 29, 2001, at A33. For a survey of international strategies to bring unaffordable HIV therapies to developing countries, see Fidler, *supra* note 130, at 301-02.

248. *Id.* ("For the millions of Africans to whom even the increasingly low-cost treatment is still out of reach, suffering and dying—without proper treatment or even diagnosis—remains the only affordable option."); cf. Kass & Hyder, *supra* note 38, at B-41 ("The current flap about AZT in Africa is a perfect case in point—the answer isn't that we shouldn't test AZT in Africa but that drug companies should not be allowed to protect their huge profit margins at the cost of blocking a South African drug company from producing AZT at a cost that Africa can afford." (quoting an anonymous researcher)). For example, in Ivory Coast, Senegal, and Rwanda, the low-cost treatment is hoped to provide treatment for up to 5000 additional people, less than one percent of those infected with HIV. Cooley, *supra* note 197, at 6.

249. *Supra* notes 11-15 and accompanying text.

250. See *Report of Working Group A: Informed Consent*, in *ETHICS AND RESEARCH ON HUMAN SUBJECTS*, *supra* note 77, at 56.

Respect for persons is an inviolable condition of all research involving human subjects. Regardless of the position of the person in the collective to which the person belongs . . . if the person is the unit of study that person must be respected. This applies even though there may be a designated "head," "leader," "spokesman" for the collective, and even though this designated "head" may authorize the research.

*Id.*

251. THE UNITED NATIONS AND INTERNATIONAL LAW JOURNAL 47 (C.C. Joyner ed., 1997), reprinted in PAUL C. SZASZ, *SELECTED ESSAYS ON UNDERSTANDING INTERNATIONAL INSTITUTIONS AND THE LEGISLATIVE PROCESS* 40 (2001).

short course AZT trials in Africa, this has become an international problem, and its resolution will require an international approach.<sup>252</sup> A convention for the protection of a subject's right of informed consent would be consistent with the attitudes of the world community, guaranteeing an additional right heretofore implicit in many other documents but not yet singled out.<sup>253</sup> The subject's right of free and informed consent is a human right, based upon the fundamental right of autonomy in decision-making, but it has not received explicit recognition in any international treaty.<sup>254</sup>

International law, in the form of a treaty, would be superior to international ethical standards.<sup>255</sup> International ethics codes lack enforcement, failing to provide penalties for their violation and compensation to their victims.<sup>256</sup> On the contrary, an international convention could obligate states to provide both criminal penalties<sup>257</sup> and civil remedies<sup>258</sup> for violation of a subject's right of informed consent.

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252. NUFFIELD COUNCIL ON BIOETHICS, *THE ETHICS OF CLINICAL RESEARCH IN DEVELOPING COUNTRIES: A DISCUSSION PAPER* 20 (1999).

The recent debate has stimulated a number of bodies including the Nuffield Council on Bioethics, the World Health Organization, the U.S. National Bioethics Advisory Commission and the U.S. National Institutes of Health to consider some of the issues arising from sponsorship of developing country clinical research by developed countries. The importance of bringing these initiatives together to form coherent guidance has already been acknowledged by many of the bodies concerned.

*Id.*

253. See, e.g., Convention on the Elimination of All Forms of Discrimination Against Women, Dec. 18, 1979, *reprinted in* 19 I.L.M. 33 (1980); International Convention on the Elimination of All Forms of Racial Discrimination, Jan. 4, 1966, *reprinted in* 5 I.L.M. 352 (1966).

254. Although international treaties have previously recognized the right of informed consent, these treaties have not been applied in the context of medical research. See, e.g., ICCPR, *supra* note 130, art. 7; see also *supra* notes 130-34 and accompanying text.

255. See Flores, *supra* note 38, at 62 ("The law is more stringent, goal centered, and formal, whereas science has traditionally been more informal, voluntary, and internalized.").

256. ANNAS & GRODIN, *supra* note 12, at 313.

257. As an example of possible criminal penalties, professors Annas and Grodin have argued in favor of an "international medical tribunal," established with the sanction and authority of the United Nations, to prosecute individual physicians found in violation of international medical standards. ANNAS, *supra* note 105, at 253. They argue that such a permanent international medical tribunal could be modeled after the International Criminal Court. ANNAS & GRODIN, *supra* note 127, at 118.

The concept of an international medical tribunal was first introduced to physicians and lawyers in 1992. Grodin et al., *supra* note 112, at 11. The idea initially failed to gain U.N. support. At the time that this tribunal was introduced, the prospects of any international criminal court were still tenuous.

*Id.* at 8 ("[W]e recognize that it may be decades before the international community agrees to establish such a [permanent international criminal court].").

Yet, even after the successes and failures in the creation of the International Criminal Court, professors Annas and Grodin continue to tout the idea of an international medical tribunal. ANNAS & GRODIN, *supra* note 127, at 119. They believe that

[t]he medical profession is the most promising candidate to take a leading role here because it has an apolitical history, it has consistently argued for at least some neutrality in wartime to aid the sick and wounded, it has a basic humanitarian purpose for its existence, and physician acts intended to destroy human health and life are a unique betrayal of both societal trust and the profession itself.

ANNAS, *supra* note 105, at 253.

Such a tribunal would serve to deter physicians from violating international norms of human experimentation. Yet, before such a tribunal can be established, a constitutive treaty—such as the



The United Nations, because of its ethical credibility and support structures, would be an ideal organ to develop this international agreement.<sup>259</sup> Further, it would be able to streamline the process of gaining international consensus, applying lessons from the failures encountered by the Council of Europe in drafting the CHR.B.<sup>260</sup> In developing appropriate treaty language, the initial work could be assigned to an existing standing organ within the United Nations—the World Health Organization. The World Health Organization, created in 1946 to unify the international regulation of infectious disease control and assist countries in scientific and public health research,<sup>261</sup> possesses both the facilities and the technical expertise to take on the preliminary studies, negotiations, and formulation of language necessary for a viable multilateral convention.<sup>262</sup> In fact, the World Health Organization has previously taken major roles in drafting conventions for the eradication of smallpox and polio.<sup>263</sup> Extending the World Health Organization's legislative powers to draft an international

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herein proposed Convention for the Protection of Informed Consent—must be created to develop the tribunal's subject matter and personal jurisdiction, mechanisms for obtaining defendant-physicians to stand trial, and international funding. Only when such a treaty is negotiated—with the input of developed states, developing states, and nongovernmental organizations—and receives widespread international support, would the International Medical Tribunal serve to punish individual physicians and deter future violations of a subject's right of informed consent.

258. With the creation of clear international law governing informed consent, civil enforcement of the right may be found in the national courts of the host country. For example, in the United States, it would be possible to grant an individual cause of action against the physician in U.S. federal court.

By granting patients access to the courts for independent review of their care, society provides a means of compensating patients who have suffered harms resulting from negligent practices, and not incidentally of deterring physicians from engaging in them.

APPELBAUM ET AL., *supra* note 11, at 219. Under this approach, a foreign subject of a U.S. physician would have a cause of action in U.S. federal court under the Alien Tort Claims Act (ATCA) for a violation of international law, specifically violation of the International Convention for the Protection of Informed Consent. See 28 U.S.C. § 1350 (1994) (establishing federal jurisdiction for “any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States”); *Filartiga v. Pena-Irala*, 630 F.2d 876 (2d Cir. 1980) (finding both subject-matter jurisdiction and a cause of action based upon human right violations against an alien).

259. ANNAS & GRODIN, *supra* note 12, at 313. Kevin King has suggested that the United Nations could accomplish this simply by developing a “Protocol on Human Experimentation” to the International Covenant on Civil and Political Rights. King, *supra* note 8, at 186.

260. See generally Arthur Rogers, *Europe: Ethical Diversity: European Community Fails to Establish Bioethics Policy*, 399 LANCET 861 (1992).

261. For a concise history of the World Health Organization, see FIDLER, *supra* note 140, at 47-52, 58-61.

262. See Constitution of the World Health Organization, July 22, 1946, art. 23, in WORLD HEALTH ORG., BASIC DOCUMENTS 1, 5 (40th ed., 1994). It should be noted that the World Health Organization (WHO) itself has quasi-legislative powers, through which it can adopt regulations (by majority vote) binding on all WHO member states unless they specifically contract out of the regulations or make reservations to them. FIDLER, *supra* note 140, at 84 (citing Constitution of the World Health Organization, *supra*, at art. 22). However, despite its authority to do so, WHO has never before adopted a formal convention and has only twice issued binding regulations. *Id.* at 60.

263. Michelle Forrest, Note, *Using the Power of the World Health Organization: The International Health Regulations and the Future of International Health Law*, 33 COLUM. J.L. & SOC. PROBS. 153, 154 (2000) (citing LAURIE GARRETT, THE COMING PLAGUE: NEWLY EMERGING DISEASES IN A WORLD OUT OF BALANCE 44-46 (1994)).

treaty regulating the methods of controlling infectious disease would require no additional United Nations authorization.

Not only is a treaty-based solution necessary, it is also feasible. Many developing nations would be willing to ratify such a treaty, since they currently have the greatest need for international medical aid and international investment in clinical research. Although developing nations would have to do the most to bring their national legislation in line with an international standard, allowing cultural variation limited to enforcement mechanisms could ease this process.<sup>264</sup>

Such an approach could be extended to multinational corporations through a global corporate compact. On January 31, 1999, United Nations Secretary-General Kofi Annan challenged world business leaders at the World Economic Forum to enact a Global Compact to reform corporate practices relating to human rights, labor, and the environment.<sup>265</sup> Specifically in the field of human rights, the Global Compact's principles would bind corporations to "support and respect the protection of international human rights within their sphere of influence; and make sure their own corporations are not complicit in human rights abuses."<sup>266</sup> This approach to nonconsensual human experimentation would place international obligations on these corporations, both through their mission statements and corporate practices. Through such an agreement, regulations could be placed on developing nations indirectly by regulating the activity of multinational corporations that perform medical testing in these regions.<sup>267</sup> This would, in turn, diminish developing nations' incentives to under-regulate human experimentation in order to create a corporate-friendly environment.<sup>268</sup> And this, combined with international and state regulation, would move developed countries toward the end of their medical exploitation of developing countries.

## VII.

### CONCLUSION

Far removed from the barbaric pseudo-scientific experiments conducted on prisoners of Nazi concentration camps, modern research is intended to cure dis-

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264. Dominguez-Urban, *supra* note 12, at 277.

265. Press Release, Secretary-General Proposes Global Compact on Human Rights, Labour, Environment, in Address to World Economic Forum in Davos, SG/SM/6881, at <http://www.un.org> (address of Secretary General Kofi Annan).

We have to choose between a global market driven only by calculations of short-term profit, and one which has a human face. Between a world which condemns a quarter of the human race to starvation and squalor, and one which offers everyone at least a chance of prosperity, in a healthy environment. Between a selfish free-for-all in which we ignore the fate of the losers, and a future in which the strong and successful accept their responsibilities, showing global vision and leadership.

*Id.*

266. Global Compact, *The Global Compact—The Nine Principles*, at <http://www.unglobalcompact.org/un/gc/unweb.nsf/content/thenine.htm>.

267. See Su-Ping Lu, *Corporate Codes of Conduct and the FTC: Advancing Human Rights Through Deceptive Advertising Law*, 38 COLUM. J. TRANSNAT'L L. 603, 604 (2000) (noting that transnational corporations often have greater influence in developing countries than do the governments of those countries).

268. See *supra* notes 119-126 and accompanying text.

ease. The only method to develop a vaccine is to perform research with human subjects. This is acceptable for, and even necessary to, the advancement of medical science.

However, this research requires risk and unforeseeable sacrifice by its subjects. Such sacrifice must always be voluntarily made if the human dignity and inviolability of the subject is to be respected.

As we in our day can smile condescendingly at the primitives and ancients who practiced human sacrifice for what they considered to be the general good of the tribe or nation, future generations may ask whether we could make human sacrifice more acceptable in our day by calling it "social cost."<sup>269</sup>

Desperate nations may not sacrifice their citizens upon the altar of medical progress.

International protections of research subjects is the only way of assuring that countries will not sidestep national regulations by exploiting developing nations with weaker protection of the research subject. Although this Article addresses the problem of human experimentation in Africa, the lessons from it have applicability throughout the developing world with a wide range of international research projects.

In 1949, judges constructed the Nuremberg Code to address the legal requirements of research upon the human body. Since that time, physicians have attempted several liberal reforms of this absolute standard, and, in doing so, have weakened the protections of the human subject in favor of the free exploration of science. For the protection of the human rights of vulnerable subjects throughout the world, scientific exploration must return to the basic principles enunciated at Nuremberg.

Returning to this standard will not be easy. Like the Nuremberg Code, an international legal standard is again needed. The Convention on Human Rights and Biomedicine shows promise for international legal regulation of human experimentation. Additional conventions with broader, worldwide acceptance are necessary to this goal.

International legal regulation would unify national regulations, providing minimum protections to the subject, regardless of his or her nationality. Inevitably this may lead to a slower progression from hypothesis to conclusion, but a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having.<sup>270</sup>

This will allow physicians to live up to the most basic credo of *primum non nocere*: do no harm.

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269. Edmond Cahn, *Drug Experiments and the Public Conscience*, in PAUL TALALAY, *DRUGS IN OUR SOCIETY* 260-61 (1964), reprinted in KATZ, *supra* note 1, at 149.

270. Jonas, *supra* note 9, at 245.