

# U.S. MEDICAL RESEARCH IN THE DEVELOPING WORLD: IGNORING NUREMBERG

Joanne Roman†

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*“The memory of Nazi Germany’s destruction of ‘other’ bodies weighs upon the design of any contemporary medical experiment that involves human subjects.”<sup>1</sup>*

## INTRODUCTION

There exists a divide between the principle that research should not proceed without the subject’s free and informed consent and the reality of human medical research.<sup>2</sup> Since the 1940s, there have been repeated efforts to create principles and rules for the protection of the human sub-

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† J.D., Cornell Law School, 2002; B.A., Rutgers College, 1999. The Author wishes to extend her deepest gratitude to Benjamin M. Meier and Renee Roman, and in particular to John and Henryka Roman, for their support.

<sup>1</sup> 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*, 9 COLUM. J. GENDER & L. 91, 92 (1999).

<sup>2</sup> George F. Tomossy & David N. Weisstub, “Consensual” Research with Cognitively Impaired Adults: Resolving Legal Shortcomings in Adult Guardianship, in RESEARCH ON HUMAN SUBJECTS 137 (David N. Weisstub ed., 1998).

jects of medical research.<sup>3</sup> Even before the relatively recent proliferation of various regulations and specifications for human medical research by various private organizations and individual nations, the Nuremberg Code was created as the first international code affirming the human rights of human research subjects.<sup>4</sup> The Nuremberg Code utilized the doctrine of informed consent as a means of protecting the human subject. This principle remains the foundation underlying human medical research ethics.<sup>5</sup> However, despite the existence of the Code and many subsequently enacted regulations, there is still considerable question as to whether these protections provide sufficient legal protection for human research subjects today. There remains a substantial gap between the espoused principle of informed consent and its actual implementation.<sup>6</sup>

This Note argues that the specific situation of AIDS vaccine testing in Africa provides evidence that the protections offered to human medical research subjects in and by the U.S. are inadequate. A new standard is necessary: the United States should adopt the Nuremberg Code into law. Part I examines the specific example of U.S. AIDS vaccine testing in Africa. Part II discusses the history of the laws governing medical research ethics, as well as current forces affecting research today. Part III of this Note suggests that the time has come for the United States to acknowledge the past failure of federal regulations to protect human subjects adequately. This requires an honest and public commitment to the respect of human rights when conducting human medical research both

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<sup>3</sup> George J. Annas, *The Changing Landscape of Human Experimentation Nuremberg: Helsinki and Beyond*, in 2 HEALTH MATRIX 119 (1992). The difficult dilemma of ethics within medical research came to the forefront as a result of the revelations concerning the experiments conducted by Nazi physicians on concentration camp prisoners during World War II. The Nuremberg Code, which resulted from the Nuremberg Trials, has remained one of the premier human rights documents regarding international research standards. *Id.* Successive sources of principles within the area of medical research ethics include the Declaration of Helsinki, CIOMS guidelines, and the Convention of Human Rights and Biomedicine. *See infra* notes 73 and 84.

<sup>4</sup> Barry R. Bloom, *The Highest Attainable Standard: Ethical Issues in AIDS Vaccines*, SCIENCE, JAN. 9, 1998, at 186. "Codification of ethical precepts for experimentation on human beings derives from the Nuremberg Code of 1947. . . . Many industrialized countries, including the United States, have established their own ethical guidelines for human experimentation, but that is rarely the case for developing countries." *Id.* *E.g.*, NAT'L COMM. FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, DHEW Pub. No. (OS) 78-0014 (Washington, D.C., U.S. Gov't Printing Office, 1988); 45 C.E.R. § 46 (1996), 21 C.E.R. § 50 (1996), 21 C.E.R. § 56 (1996); U.S. PUBLIC HEALTH SERVICE, CONSULTATION ON INTERNATIONAL COLLABORATIVE HUMAN IMMUNODEFICIENCY VIRUS (HIV) RESEARCH (1990).

<sup>5</sup> Dyckman, *supra* note 1, at 96 (noting that "[t]he Nuremberg Code's emphasis on the notion of informed consent has been affirmed by several successive declarations and codes concerning human experimentation").

<sup>6</sup> David J. Rothman, *Bringing Ethics to Human Experimentation: The American Experience*, in RESEARCH ON HUMAN SUBJECTS (David N. Weisstub ed., 1998).

at home and abroad. The U.S. can achieve this by adopting the Nuremberg Code and affirm its commitment to the Code's basic principles. This implementation could be the very impetus necessary to bridge the gap between professed ideals and practice, ushering in a true realization of informed consent for all humanity.

### I. AIDS VACCINE TRIALS IN AFRICA

AIDS has relentlessly impacted developing countries.<sup>7</sup> UNAIDS and WHO estimate that the number of people living with HIV or AIDS at the end of the year 2000 was 36.1 million.<sup>8</sup> The combined statistics of SubSaharan Africa, North Africa and the Middle East of both adults and children living with HIV/AIDS was 25.7 million.<sup>9</sup> As a result, Africa is home to 70% of the adults and 80% of the children living with HIV in the world. African countries are faltering from the devastating impact of this disease.<sup>10</sup>

The scientific community has declared that the best and most likely hope for stemming this global epidemic is the development of yet-undiscovered preventative HIV vaccines.<sup>11</sup> The FDA approved the first drug, zidovudine, commonly known as AZT, for use against HIV and AIDS in 1987.<sup>12</sup> In February 1994, the Data Safety and Monitoring Board of the U.S. National Institute of Allergies and Infectious Diseases found a significant positive result in children born to HIV positive mothers, when the pregnant women, infected with HIV, received zidovudine (AZT).<sup>13</sup> The trials conducted in France and the United States found that a regimen during the later stages of pregnancy could reduce the chance of HIV

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<sup>7</sup> Bloom, *supra* note 4, at 186.

<sup>8</sup> Global Summary of the HIV/AIDS Epidemic, December 2000, at [http://www.unaids.org/wac/2000/wad...port/css/WAD\\_epidemic\\_report\\_3.htm](http://www.unaids.org/wac/2000/wad...port/css/WAD_epidemic_report_3.htm) (last visited July 5, 2001).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

In South Africa, the epidemic is projected to reduce the economic growth rate by 0.3–0.4% annually, resulting by the year 2010 in a gross domestic product (GDP) 17% lower than it would have been without AIDS and wiping US\$ 22 billion off the country's economy. Even in diamond-rich Botswana, the country with the highest per capita GDP in Africa, in the next 10 years AIDS will slice 20% off the government budget, erode development gains, and bring about a 13% reduction in the income of the poorest households.

*Id.*

<sup>11</sup> Bloom, *supra* note 4, at 186. Many developing countries are unable to afford drug therapies, leaving only counseling to decrease potentially harmful behavior. *Id.*

<sup>12</sup> John Henkel, *Attacking AIDS with a 'Cocktail' Therapy*, FDA CONSUMER, July-Aug. 1999, at [http://www.fda.gov/fdac/features/1999/499\\_aids.html](http://www.fda.gov/fdac/features/1999/499_aids.html) (last visited Feb. 25, 2002).

<sup>13</sup> 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 (1998). The information found was part of a study that was interrupted and the findings were based on preliminary data.

transmission to the child by two-thirds.<sup>14</sup> However, the treatment was prohibitively expensive, costing nearly \$1,000 per patient, thereby making it unavailable to most women in developing countries.<sup>15</sup> “Short course” AZT trials were suggested to determine whether less-expensive alternatives could produce the same effects while reducing the amount of AZT needed to block transmission of HIV from mother to child.<sup>16</sup> These trials would experiment with the variations of already known drug regimens of AZT in an effort to find a drug regimen that was both less complex to administer and less expensive. The trial also included a control group destined solely to receive placebos.<sup>17</sup>

#### A. U.S. INVOLVEMENT

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) paid for and developed these trials “aimed to test the efficacy of a “short course” of AZT . . . in preventing perinatal transmission of HIV.”<sup>18</sup> Beginning in 1997, CDC and NIH conducted studies involving more than 12,000 women in countries including Thailand, the Dominican Republic, and several African countries.<sup>19</sup> These studies were specifically designed so that half of the mother-participants would receive a placebo.<sup>20</sup> It is estimated that more than 1,000 babies contracted the AIDS virus because of the placebo treatment given to their mothers.<sup>21</sup>

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<sup>14</sup> Dyckman, *supra* note 1, at 92. This study was known as AIDS Clinical Trial Group (ACTG) Study 076. *Id.* at 92 n.5, citing Sheryl Gay Stolberg, *U.S. AIDS Research Abroad Sets off Outcry Over Ethics*, N.Y. TIMES, Sept. 18, 1997, at A1. The ACTG 076 regimen required the subject mother to take AZT five times a day for the last six months of her pregnancy and intravenously during labor, and the infant to have AZT four times a day for six weeks. *Id.*

<sup>15</sup> Dyckman, *supra* note 1, at 92. The sad irony of the success of AZT was that the treatment was affordable only in industrial nations, where mother-fetal transmissions are a more limited problem, denying AZT use in regions where it was tested. It is specifically in developing countries, “where maternal-fetal transmission represents an epidemiologically significant disaster, [that] the costs of prophylactic treatment (disregarding the absence of the infrastructure necessary for intravenous treatment during delivery) put treatment with zidovudine out of reach.” Bayer, *supra* note 13, at 567.

<sup>16</sup> 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. 738 (2000).

<sup>17</sup> Bloom, *supra* note 4, at 186. The short-course of AZT consists of oral AZT in the last four weeks of pregnancy as well as during labor. Todres, *supra* note 16, at 737.

<sup>18</sup> Todres, *supra* note 16, at 738.

<sup>19</sup> Dyckman, *supra* note 1, at 92; Todres, *supra* note 16, at 737 n.1 (“There had been sixteen clinical trials ongoing at sites in Burkina Faso, the Dominican Republic, Ethiopia, the Ivory Coast, Kenya, Malawi, South Africa, Tanzania, Thailand, Uganda, and Zimbabwe. Nine of the studies were funded by the CDC or the National Institutes for Health (NIH), both U.S. Government agencies. In total, fifteen of the trials involved the use of placebos.”).

<sup>20</sup> Dyckman, *supra* note 1, at 93.

<sup>21</sup> *Id.*

## B. OPPOSITION

Those opposed to the short course AIDS vaccine research in developing countries questioned the lack of respect for the Nuremberg Code evident in these experiments.<sup>22</sup> Critics also claimed that the evidence resulting from the earlier French and American experiments would be an adequate measure by which to compare the effect of the short course AZT treatment. As a result, a placebo control is unnecessary.<sup>23</sup>

Former U.S. Senator Carol Moseley Braun (D-IL) publicly denounced the federal government for funding AIDS research experiments on women in developing countries.<sup>24</sup> Senator Moseley-Braun suggested that these experiments violated the World Health Organization guidelines, which mandate that a treatment can only be compared to a placebo when there is no known effective treatment available, instead, subjects in the research group must receive the “best known treatment.”<sup>25</sup> Public Citizen, a Washington, D.C. based interest group publicly decried the trials as violations of the Nuremberg Code, stating: “Researchers involved in these experiments have exploited the inadequacies of the health-care systems in these developing countries to conduct research they would never even consider in the U.S.”<sup>26</sup>

The informed consent employed in the AZT trials in Africa is problematic at best, considering the contrasting positions of knowledge, authority and wealth between the researchers and test subjects.<sup>27</sup> There is evidence that suggests the subjects of the experiment did not give the requisite informed consent as required by the Nuremberg Code.<sup>28</sup> There

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<sup>22</sup> *Id.* at 92.

<sup>23</sup> Marcia Angell, *The Ethics of Clinical Research in the Third World*, 337 *NEW ENG. J. MED.* 847, 849 (1997) (referencing ACTG Study 076).

<sup>24</sup> Chinta Strausberg, *U.S. Funded Experiment Unethical*, N.Y. BEACON, Oct. 15, 1997.

<sup>25</sup> *Id.*

<sup>26</sup> Letter to the Department of Health and Human Services Concerning Unethical Studies Which Used Placebos on HIV-Positive Pregnant Women in Developing Countries (April 22, 1997), at <http://www.citizen.org/publications/release.cfm?ID=6627> (“On this 50<sup>th</sup> year since the commencement of the Nuremberg doctor trials, it is disheartening in the extreme that, at a minimum, four of the ten principles of the Code have been abrogated in this research.”).

<sup>27</sup> Dyckman, *supra* note 1, at 102.

<sup>28</sup> *Id.* at 98-99.

Testimony from some of the African participants in these studies offers compelling reasons to doubt the sufficiency of informed consent, regardless of the researchers’ good intentions; indeed, many participants have expressed confusion about the test. One twenty-three-year-old infected mother was questioned repeatedly by a journalist about what a placebo is and why it was being used. She responded, “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 knew 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.” Like many of the participants, this mother was illiterate, unemployed, and unmarried. A reporter for the *New York Times*, Howard French, noted that this mother’s reasons for enrolling in these tests were clear to her: “It

were also subjects of the AZT study who chose to participate even after full disclosure, but it was their lack of financial resources and access to the treatment that ultimately influenced their decision to join the study.<sup>29</sup> All of this information contrasts starkly with the assertion by the CDC that “[w]omen [were] clearly told that the AZT regimen might or might not be effective. . . . It [was] clearly explained to the women involved that some would receive AZT and others would receive a placebo.”<sup>30</sup>

This reality is compounded when the specific social and economic elements of Africa are revealed.<sup>31</sup> The present social order: the fifty-percent higher illiteracy rate for women, the inability of women to own property in several African nations, and the “pervasive attitude that women must yield sexual decision-making to men,”<sup>32</sup> both subordinates women and increases the probability of the spread of HIV as well as the probability of involuntary consent. During the U.N. Global Conference on HIV/AIDS in June 2001, the vulnerability of women with regards to contracting AIDS was specifically discussed. The Declaration of Commitment adopted by the General Assembly declared that the empowerment of women was necessary to lower their vulnerability.<sup>33</sup> Given the totality of the situation for the women-subjects, it is questionable whether their decision can truly be labeled either informed or consensual.<sup>34</sup>

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offered her and her infant free health care and a hope to shield her baby from a deadly infection.”

*Id.* at 98-99, quoting Howard W. French, *AIDS Research in Africa: Juggling Risks and Hopes*, N. Y. TIMES, Oct. 9, 1997, at 1A. This was not an isolated incident. The journalist conducted interviews with other subjects in the study and found that many did not actually understand the issues involved. *Id.*

<sup>29</sup> Dyckman, *supra* note 1, at 99-100. “[O]ther mothers, . . . French reports, ‘acknowledged that they understood little’ of the tests but hoped to save their children or get ‘free health care’ that they could not otherwise afford.” *Id.* at 100. It is the situation itself in Africa that makes the experiments inherently coercive. By comparison, a breast cancer research experiment conducted in Britain that utilized placebos clearly showed how the country in which the study is held may in fact influence the study itself. The British study had a difficult time getting volunteers to participate in a study testing a new drug that purported to prevent breast cancer in those who were at high risk. One British researcher involved commented that people with financial resources do not have to accept the consequences of a placebo when they are in a position to receive treatment with known results. Charles Arthur, *Science: Are Scientific Trials Blind to Suffering?*, INDEP. (London), Oct. 28, 1997, at N8.

<sup>30</sup> Dyckman, *supra* note 1, at 100 n.33 (citing Charles W. Henderson, *CDC Explains Its Stand on Controversial Third World AZT Study*, AIDS WEEKLY PLUS, July 28, 1997).

<sup>31</sup> *Id.* at 101.

<sup>32</sup> *Id.* at 101, n.36.

<sup>33</sup> Famaz Fassih, *Empower Women to Help AIDS War, U.N. Strategy Says*, STAR LEDGER, Jul. 1, 2001, at 3. In many African countries, women cannot refuse unwanted or unprotected sex, nor can they create safe sex, even in marriages. *Id.*

<sup>34</sup> *Id.* See also MARTHA ALBERTSON FINEMAN, *THE NEUTERED MOTHER, THE SEXUAL FAMILY AND OTHER TWENTIETH CENTURY TRAGEDIES*, 190 (questioning whether women on welfare, when offered financial incentives to use Norplant, can truly be said to be in a “voluntary” position considering their economic status and personal circumstances).

### C. REACTIONS

Those in favor of the trials dismissed the argument that the trials were unethical.<sup>35</sup> The head of the NIH, Harold Varmus, the head of the CDC, David Satcher, as well as Michael Merson, the executive director of the WHO Global Program on AIDS, vigorously supported the trials.<sup>36</sup> The proponents claimed that the actual question was whether it was ethical to conduct such trials in a developing country where the therapy would have been unavailable anyway.<sup>37</sup> Under this reasoning, the AZT drug trial was thereby justifiable on the basis that *no treatment* was the actual standard of care in Africa.<sup>38</sup> Proponents argued, with a relativist perspective, that it was unreasonable to impose “burdensome American values and requirements on other nations.”<sup>39</sup> Because Africa is a community-centered society, rather than an individual-centered society such as the United States, the oversight necessary in the United States would not be appropriate in Africa, argued proponents.<sup>40</sup> This view is reflected in the CIOMS Guidelines. The CIOMS Guidelines of 1982 address the issue of obtaining informed consent in community-centered societies by working through intermediaries, or community leaders.<sup>41</sup> However, the proponents of the research risk confusing what is culturally relative with economic inequality in order to support their view.<sup>42</sup>

On February 17, 1998, the CDC unexpectedly announced the end of the short course AIDS vaccine research in Africa because of the adequacy of the results obtained from the drug research in Thailand, the first available results from the study.<sup>43</sup> This announcement abruptly halted

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<sup>35</sup> Bayer, *supra* note 13, at 567 (arguing that this trial is unlike Tuskegee, in which there was actual concerted effort to keep the subjects from receiving therapy); Joseph Saba & Arthur Amann, *Drug Tests Offer Hope to Victims*, ARIZ. REPUBLIC, Sept. 23, 1997, at B7.

<sup>36</sup> Harold Varmus & David Satcher, *Ethical Complexities of Conducting Research in Developing Countries*, 337 NEW ENG. J. MED. 1003, 1005 (1997). Beyond the specific example of the AIDS trials, there are those who criticize the reliance on informed consent as a marker for acceptable medical research in general, labeling it as simply too idealistic: “we follow it like a signpost pointing the way to our ideal of relations based on equality and respect.” Richard W. Gamett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW 455, 508 (1996).

<sup>37</sup> Bayer, *supra* note 13, at 567. The question framed by those in favor of the research then becomes: “What is the standard of care in this particular developing nation?”

<sup>38</sup> Dr. David D. Ho, *It's AIDS, Not Tuskegee; Inflammatory Comparisons Won't Save Lives in Africa*, TIME, Sept. 29, 1997, at 83.

<sup>39</sup> Dyckman, *supra* note 1, at 104.

<sup>40</sup> *A Growing Dichotomy: The Gap Between Therapeutic Haves and Have-Nots*, AIDS ALERT, Jan. 1, 1998.

<sup>41</sup> World Health Org. & Council for Int'l Org. of Med. Science, *Proposed International Guidelines for Biomedical Research Involving Human Subjects*, reprinted in HUMAN EXPERIMENTATION AND MEDICAL ETHICS (Zbigniew Bankowski & Norman Howard-Jones eds., 1982).

<sup>42</sup> Dyckman, *supra* note 1, at 109.

<sup>43</sup> Todres, *supra* note 16, at 737 n.1.

the ever-controversial research, which had been surrounded by questions, criticisms, and ardent support from its very beginnings.<sup>44</sup>

## II. MEDICAL RESEARCH STANDARDS: A HISTORICAL OVERVIEW

### A. THE NUREMBERG CODE

Following World War II, Nazi physicians who experimented on their prisoners during the war were tried before the Military Tribunal at Nuremberg.<sup>45</sup> The Tribunal explained that any human medical experimentation had to remain within certain specifically delineated boundaries to comply with acceptable norms of ethical human research.<sup>46</sup> The judges viewed the experimentation performed by the Nazi researchers as “horrendous non-therapeutic, nonconsensual prison research”<sup>47</sup> well outside the bounds of medical ethics and international law. Those involved in the experiments were prisoners in Nazi concentration camps—mostly Jews, Gypsies and Slavs.<sup>48</sup>

The Military Tribunal based the Nuremberg Code on natural law, protecting individual rights over the right of the researcher to his or her scientific endeavor.<sup>49</sup> This concept was a direct response to the view in Nazi Germany that certain groups were simply not worthy of “medicine or bodily integrity because of social or political construction of their bodies as inferior.”<sup>50</sup> It was a focused attempt to prevent the horrors that created its very existence.<sup>51</sup> The Code set forth two key concepts: 1) that the informed consent of the human research subject is required and 2)

<sup>44</sup> *Id.* at 737.

<sup>45</sup> Annas, *supra* note 3, at 120. U.S. judges sat in judgement of these very experimenters and therefore became an integral part of the creation of the Nuremberg Code. Beyond simply using American judges, the prosecutors and the criminal procedure rules at Nuremberg were also American. Kevin M. King, *A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 ST. J. I. L. 163, 167 n.26 (1998).

<sup>46</sup> Michelle D. Miller, Note, *The Informed-Consent Policy of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use: Knowledge Is the Best Medicine*, 30 CORNELL INT’L L.J. 203, 204 (1997). Before World War II, the legal issues surrounding medical experimentation were largely absent from the American public. The evidence of the medical experiments conducted by Nazi doctors forced the issue to the attention of Americans for the first time. *Id.*

<sup>47</sup> Annas, *supra* note 3, at 119.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*; Dyckman *supra* note 1, at 91 (“Called the Nuremberg Code, this document provides guidance to those in the medical field by structuring a means to achieve the goal of securing the bodily integrity of each human subject.”).

<sup>50</sup> Dyckman, *supra* note 1, at 119.

<sup>51</sup> *Id.* at 95. Although references to “voluntary” consent and “free power of choice” “clearly envision the doctrine’s application in a context involving autonomous, empowered individuals,” the Nazi experiments were not an example of the same. *Id.*

that research is not justified simply based on the fact that the subject gave informed consent.<sup>52</sup>

The first principle of the Nuremberg Code requires consent that is voluntary, informed, competent, and made with true understanding.<sup>53</sup> But informed consent is not the only condition. There are eight other provisions of the Nuremberg Code which relate to the welfare of the research subject and must be satisfied before seeking the subject's informed consent.<sup>54</sup> The research subject cannot voluntarily waive any of these requirements.<sup>55</sup> These additional requirements include the creation of a valid research design seeking otherwise unobtainable information that is important for the good for all of society; the avoidance of unnecessary suffering and injury; no actual reason to believe that death or disabling injury will result from the research; the determination that benefits surpass possible risks; the right to withdraw from the experiment; and the involvement of a qualified researcher who is prepared to end the research if it "is likely to result in the injury, disability, or death of the experimental study."<sup>56</sup>

The international status of the Nuremberg Code was cemented with the creation and widespread ratification of the International Covenant on Civil and Political Rights which incorporated the consent requirement.<sup>57</sup> In addition, because the Nuremberg Code was based on international natural law and ethics, its standard cannot be lowered by any group of researchers. It is also true that no rule in any individual country can

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<sup>52</sup> Todres, *supra* note 16, at 743.

<sup>53</sup> THE NUREMBERG CODE, *reprinted in* THE NAZI DOCTOR AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION (George J. Annas & Michael Grodin, eds., 1992) at 2.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> Annas, *supra* note 3, at 121, *quoting* The Nuremberg Code:

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.

<sup>57</sup> M. Gregg Bloche, *Beyond Consent*, in RESEARCH ON HUMAN SUBJECTS 44, 55 n.22 (David N. Weissstub ed., 1998).

derogate from the international standards expressed in the Nuremberg Code.<sup>58</sup>

The Code then clearly holds as its priority, the informed consent of any human research subjects.<sup>59</sup> The particular subject involved in the model of informed consent is assumed to be a rational decision-maker participating only after having been given all relevant information and having evaluated the risks and benefits according to his or her own personal set of values.<sup>60</sup> However, as the terms and concepts become more common in medical research parlance, the possible interpretations of the terms of the Nuremberg Code become more variable.<sup>61</sup>

The theory underlying informed consent must be coupled, and contrasted, with the presumed physician/researcher authority under the paternalistic ideology of medical professionalism.<sup>62</sup> Not only are subjects of a disease vulnerable because of their physical suffering, but there is also vulnerability as a result of the unequal relationship between the subject and the doctor-researcher.<sup>63</sup> The subject cannot recover without the doctor-researcher, and the doctor appears to hold the knowledge that will heal the subject-patient. However, in order to receive this desired help, the patient necessarily must place him or herself into the doctor's care and thereby trust the abilities of the researcher.<sup>64</sup> This signature is especially important in human research because the patient is simultaneously a research subject.<sup>65</sup> Historically, physicians have espoused the theory that their patients' needs are always best served by following doctor's orders; a benevolent form of paternalism. The physician's demand of complete control over the patient and his or her needs, and the belief that they can be trusted to safeguard their patients, is propelled further by the assumption that the patients themselves are simply unable to comprehend the depths of medicine's knowledge.<sup>66</sup> The doctrine of informed consent

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<sup>58</sup> Annas, *supra* note 3, at 124.

<sup>59</sup> Jonathan D. Moreno, *Lessons Learned: A Half-Century of Experimenting on Humans*, *THE HUMANIST*, Sept./Oct. 1999, at 9; Miller, *supra* note 46, at 207-08.

Given that the judgment originated from a U.S. trial complete with U.S. judges, prosecutors, and criminal procedure, an objective observer might have expected that U.S. courts would use the Nuremberg Code as the legal standard for medical experimentation. However, it was not until 1973, more than twenty-five years later, that any court cited the Code. The delay might be partially attributable to the extreme nature of the Nazi experiments—no court wanted to compare an American doctor to a Nazi physician.

<sup>60</sup> *Id.*

David N. Weisstub, *Roles in Clinical and Research Ethics*, in *RESEARCH ON HUMAN SUBJECTS* 56, 69 (David N. Weisstub ed., 1998).

<sup>61</sup> Annas, *supra* note 3, at 123.

<sup>62</sup> Jay Katz, *Human Experimentation and Human Rights*, *ST. LOUIS U. L.J.* 7, 18 (1993).

<sup>63</sup> David C. Thomasma & Edmund D. Pellegrino, *Medicine, Science, Self-Interest: Value Sets in Conflict*, in *RESEARCH ON HUMAN SUBJECTS* (David N. Weisstub ed., 1998).

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> Katz, *supra* note 62, at 19.

has done little to moderate the idealized opinion of physician authority, leaving the decision-making process still generally under physician control.<sup>67</sup>

## B. THE DECLARATION OF HELSINKI

For all of its international weight, physicians and researchers criticized the Nuremberg Code both for the way it was created as well as for its substantive deficiencies.<sup>68</sup> Because judges created the Code, and not other researchers, physician-researchers thought the Code inapplicable to their own practices. Physicians believed that Nuremberg itself did not have much to do with the medical establishment, it had to do only with war crimes.<sup>69</sup> Although doctors were involved as witnesses in the trial and were also called as consultants, the Nuremberg Code itself was created by judges, realized through a court, and established without medical professional standing.<sup>70</sup> As such, the Code was truly outside medicine. This externality suggested to Americans that the Code was in no way relevant to them.<sup>71</sup> Additionally, judges made no particular attempt to deal with special issues, such as children, patients, or the mentally-impaired. As a result, physicians found the Code confining and more aptly described as a human rights document.<sup>72</sup> This criticism resulted in a proliferation of more permissive alternative documents governing human experimentation, one being the Declaration of Helsinki adopted by the World Medical Assembly in 1964.<sup>73</sup> In direct response to the problems physicians perceived in the Nuremberg Code, this new Declaration consisted merely of recommendations by physicians to physicians.<sup>74</sup> The goal of the Declaration was to establish a more relaxed medical ethics

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<sup>67</sup> Katz, *supra* note 62, at 20. In practice, the general concepts of disclosure and consent are consistently taken lightly because doctors/researchers do not consider patient/research subjects as equals. *Id.* at 23-24.

<sup>68</sup> Annas, *supra* note 3, at 122. Those who dismiss the Code say it is simply too demanding and idealistic. Gamett, *supra* note 36, at 473. “[I]ts standards are too high for necessary research to meet, and . . . its absolutism cannot compete with the utilitarian and impersonal ethics of modern medicine.” *Id.* at 472.

<sup>69</sup> Rothman, *supra* note 6, at 35.

<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 35-36 (noting that the Code was contemporaneous with the Cold War as well as the public health campaign to eradicate disease).

<sup>72</sup> Annas, *supra* note 3, at 122.

<sup>73</sup> DECLARATION OF HELSINKI RECOMMENDATIONS GUIDING DOCTORS IN CLINICAL RESEARCH, *reprinted in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 331, e331 (George J. Annas & Michael Grodin eds., 1992) (1964). The Helsinki Declaration was first promulgated in 1964 and amended three times since. Annas, *supra* note 3, at 122.

<sup>74</sup> Annas, *supra* note 3, at 122. In fact, the Declaration was subtitled “recommendations guiding doctors in clinical research.” *Id.*

model that permitted paternalism,<sup>75</sup> expressing a more “benign modern attitude toward biomedical research.”<sup>76</sup>

The essence of the Declaration divides research into the therapeutic and the non-therapeutic, allowing for paternalism in the exceptions afforded therapeutic research.<sup>77</sup> Therapeutic research is said to extend to the subject an acceptable probability that the research/therapy will be helpful to the health of the subject, having as its ultimate objective, the well-being of the subject.<sup>78</sup> Research and experimentation, or non-therapeutic research, is said to benefit the advancement of knowledge and society as a whole, such that the overriding objective is to serve scientific knowledge generally.<sup>79</sup> However, these categories are not absolute nor are they mutually exclusive. There may be research situations where it cannot readily be determined where the benefit lies.<sup>80</sup>

In 1964, the Declaration of Helsinki adopted an informed consent provision.<sup>81</sup> However, the Declaration claims the following two concerns as priority: “first, that the individual human subject’s health is valued over competing gains to others, and second, that the best known treatment available be used.”<sup>82</sup> This tension between the *required* informed consent stressed in the Nuremberg Code and the *preferred* prior peer review in The Declaration of Helsinki has led physicians to all but abandon the Code in favor of the more lenient Declaration.

<sup>75</sup> *Id.* “U.S. researcher Henry Beecher probably best expressed medicine’s delight with the Declaration of Helsinki’s ascendancy when he said in 1970: ‘The Nuremberg Code presents a rigid act of legalistic demands . . . . The Declaration of Helsinki, on the other hand, presents a set of guides. It is an ethical as opposed to a legalistic document and is thus more broadly useful than the one formulated at Nuremberg.’” *Id.* at 122-23.

<sup>76</sup> Wendy K. Mariner, *AIDS Research and the Nuremberg Code*, in *THE NAZI DOCTORS AND THE NUREMBERG CODE* 286, 289 (George J. Annas & Michael A. Grodin eds., 1992).

<sup>77</sup> Annas, *supra* note 3, at 123. Therapeutic is defined as “Medical Research Combined with Professional Care.” *Id.*; see also Miller, *supra* note 46, at 209 (describing non-therapeutic experimentation which has as its only purpose, to test a hypothesis, and therapeutic research, created to help the human subject as well as aid the researcher).

<sup>78</sup> Simon N. Verdun-Jones & David N. Weisstub, *Drawing the Distinction Between Therapeutic Research and Non-Therapeutic Experimentation: Clearing a Way Through the Definitional Thicket*, in *RESEARCH ON HUMAN SUBJECTS*, *supra* note 2, at 92. It understandably seems that there is less to fear in therapeutic research because the end goal is to help that particular research subject. But even these subjects could be led to believe that they are receiving a known cure and not simply testing a *possible cure*. See Mariner, *supra* note 76, at 292.

<sup>79</sup> Verdun-Jones & Weisstub, *supra* note 78, at 93.

<sup>80</sup> *Id.* at 98. The Random Clinical Trial is just one example where the objectives may be mixed. A subject may be cured by the treatment, but in such trials, the different treatments are not specifically created for the subject and the one subject’s end result is not the specifically desired outcome. *Id.* at 104-05.

<sup>81</sup> Dyckman, *supra* note 1, at 96. “Strengthening the informed consent provision in later declarations, in 1989 the Declaration of Helsinki of the World Health Organization issued ethical guidelines concerning informed consent . . .” *Id.*

<sup>82</sup> Dyckman, *supra* note 1, at 97. Only the Nuremberg Code holds informed consent as a core principle. *Id.*

### C. CIOMS GUIDELINES

Another set of standards arising from the dissatisfaction with Nuremberg principles was a joint project in 1982 between WHO (the World Health Organization) and CIOMS (the Council for International Organizations of Medical Sciences), creating the Guidelines for Medical Ethics in Biomedical Research.<sup>83</sup> The creators of the Guidelines felt that the informed consent of the Nuremberg Code was inadequate as a basis for protection, and instead, worked to prevent abuses.<sup>84</sup> These Guidelines are unique in international regulations because they offer the basic ethical principles under which all human research projects ought to be formulated.<sup>85</sup> The basic principles include “respect for persons, beneficence and justice.”<sup>86</sup> The Guidelines were meant to support and help implement Helsinki IV.<sup>87</sup> These Guidelines were created with the help of drug regulatory agencies from WHO’s member states and purposefully set out to create globally applicable standards of human medical research.<sup>88</sup> But the Guidelines were not offered as legal text, rather, it was offered as a framework which countries could use to build their own respective regulations.<sup>89</sup> As a result, despite the positive attributes of the ethical Guidelines, they are utterly unenforceable without voluntary enactment by a nation’s legislature or a specific application by a nation’s judiciary.<sup>90</sup>

### D. AMERICAN MEDICAL RESEARCH REGULATIONS

The AZT trials in Africa are not the only example of U.S. medical researchers disregarding Nuremberg principles.<sup>91</sup> One of the most notorious examples was the Fort Detrick, Maryland LSD experiments from

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<sup>83</sup> COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES, INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (GENEVA: CIOMS, 1993). The Guidelines were published as the International Ethical Guidelines for Biomedical Research Involving Human Subjects. King, *supra* note 45, at 182. The Guidelines were revised in 1991. *Id.*

<sup>84</sup> King, *supra* note 45, at 182-83. Unlike the Declaration of Helsinki (at least before 1989), the Guidelines required all experiments involving human research subjects to pass through the review of an IRB. *Id.* at 183. The Guidelines also included statements on vulnerable populations, compensation for injury, and research in developing nations. *Id.*

<sup>85</sup> Sev S. Fluss, *The Regulation of Human Experimentation: Historical and Contemporary Perspectives*, in RESEARCH ON HUMAN SUBJECTS 222, 229 (David N. Weisstub ed., 1998).

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 229-32.

<sup>89</sup> King, *supra* note 45, at 182.

<sup>90</sup> *Id.* at 184.

<sup>91</sup> Miller, *supra* note 46, at 210 n.45. Given that the judgment originated from a U.S. trial complete with U.S. judges, prosecutors, and criminal procedure, an objective observer might have expected that U.S. courts would use the Nuremberg Code as the legal standard for medical experimentation. However, it was not until 1973, more than twenty-five years later, that any court cited the Code. The delay might be partially attributable to the extreme nature

1953 through 1971, where “approximately 6,700 human subjects were used by the [United States] government in experiments involving psychoactive chemicals. In private contract research with universities and chemical companies, other agents were also used, including morphine, Demerol, Seconal, mescaline, atrophine, and psilocybin.”<sup>92</sup> Furthermore, the Supreme Court refused to allow a suit against the United States for injuries resulting from these experiments, labeling them as “incident to service” under the legal Feres Doctrine.<sup>93</sup> In his failed attempt to have the U.S. Supreme Court recognize the Nuremberg Code within the U.S. armed forces, Master Sergeant James B. Stanley was barred from suing the United States for involving him in LSD experiments without his knowledge or consent after a 5-4 vote.<sup>94</sup>

Another infamous example was the Tuskegee Syphilis Study, conducted by Public Health Service physicians from 1932 through 1972, where penicillin was denied to nearly 400 uninformed, poor, African-American sharecroppers in order to track the normal course of the disease.<sup>95</sup> In 2001, a research subject died after participating in an asthma experiment conducted by Johns Hopkins researchers.<sup>96</sup> Preliminary findings noted failures by the researchers in reporting previous reactions, in following the plan of preparation for the administered drug and in notifying the subject that the drug was experimental.<sup>97</sup> The need for the United States to adopt the Nuremberg Code and ratify the informed consent principle contained within is more urgent than ever.

In general, the federal regulations currently available are much more permissive regarding human medical research than the Nuremberg Code.<sup>98</sup> The federal government became involved in the regulation of human medical research beginning in 1962.<sup>99</sup> The impetus for federal involvement resulted after a series of exposés concerning unethical research generated public outcry in the 1960s and early 1970s. These exposés, in turn, placed pressure on the federal government, or more

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of the Nazi experiments—no court wanted to compare an American doctor to a Nazi physician. *Id.* at 207-08. Moreno, *supra* note 59, at 9.

<sup>92</sup> Moreno, *supra* note 59, at 9.

<sup>93</sup> *Id.* at 10.

<sup>94</sup> *Id.* at 9-10; *U.S. v. Stanley*, 483 U.S. 669 (1987).

<sup>95</sup> Katz, *supra* note 62, at 8 n.3.

<sup>96</sup> Laurence K. Altman, *F.D.A. Faults Johns Hopkins Over Process in Fatal Asthma Study*, N.Y. TIMES, July 3, 2001; Gina Kolata, *Johns Hopkins Admits Fault in Fatal Experiment*, N.Y. TIMES, July 17, 2001. Johns Hopkins accepted full responsibility for the death, reporting that the researcher and the ethics committee failed to adequately protect the research subject. *Id.*

<sup>97</sup> Kolata, *supra* note 96.

<sup>98</sup> Leonard H. Glantz, *The Influence of the Nuremberg Code on U.S. Statutes and Regulations*, in *THE NAZI DOCTORS AND THE NUREMBERG CODE* 183, 198 (George J. Annas & Michael A. Grodin eds., 1992).

<sup>99</sup> *Id.* at 186. The FDA became involved after the Drug Amendments Act of 1962. *Id.*

specifically, the National Institutes of Health (NIH), to establish regulations for human research.<sup>100</sup> The impact of the public disapproval was intensified because the federal government was the usual source of funds for such research.<sup>101</sup> The NIH gave the grants and the NIH received its funds from Congressional appropriations.<sup>102</sup>

But it was not until 1966 that the FDA created patient consent regulations clarifying the federal government's policy on consent in medical research.<sup>103</sup> Also in 1966, the NIH began the policy of requiring Institutional Review Boards (IRBs) to review research in order to obtain or continue grants, thereby beginning the U.S. institutional focus.<sup>104</sup> The protection of the IRBs became the chosen federal option, instead of a permanent regulatory commission,<sup>105</sup> showcasing the general tone of federal involvement: attempting to protect subjects but not if such protection would hinder important research.<sup>106</sup>

The regulation of research by IRBs was started into motion by Surgeon General William Stewart in 1966, by Policy and Procedure Order 129 (PPO 129).<sup>107</sup> That policy has been expanded and revised considerably until it reached its current position where IRBs are now required by sixteen departments and agencies of the federal government, which includes all research by the FDA.<sup>108</sup> The main objective of the IRB is to protect a human research subject's rights and general welfare.<sup>109</sup> IRBs

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<sup>100</sup> Rothman, *supra* note 6, at 39. One publication was in 1966 by Harvard Medical School professor Henry Beecher, "Ethics and Clinical Research" in *The New England Journal of Medicine* which described twenty-two experiments that were seriously questionable in terms of ethicality. *Id.* In order to make the information more widely known, Beecher brought news of the article to the general press which spearheaded the later public outcry. *Id.* This public outcry was consistent with the general feeling of social consciousness evident in the 1960s. *Id.*

<sup>101</sup> *Id.* at 41.

<sup>102</sup> *Id.*

<sup>103</sup> Glantz, *supra* note 98, at 198.

<sup>104</sup> *Id.* The IRB was not involved in Nuremberg, but it has been one of the only advances since Nuremberg. It can be seen as an additional protection when relying on consent is not enough to protect the subject's rights.

<sup>105</sup> Bernard Starkman, *Models for Regulating Research: The Council of Europe and International Trends*, in *RESEARCH ON HUMAN SUBJECTS* 264, 266-67 (David N. Weisstub ed., 1998).

<sup>106</sup> Glantz, *supra* note 98, at 187. The Declaration of Helsinki also calls for IRBs. "The design and performance of each experiment procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance." Annas, *supra* note 3, at 123 (quoting Principle I.2 of the 1989 revision of the Declaration (Helsinki IV)).

<sup>107</sup> Charles R. McCarthy, *The Institutional Review Board: Its Origins, Purpose, Function, and Future*, in *RESEARCH ON HUMAN SUBJECTS* 301, 307 (David N. Weisstub ed., 1998).

<sup>108</sup> *Id.* at 316.

<sup>109</sup> *Id.*; Dale L. Moore, *Recurrent Issues In the Review of Medical Research on Human Subjects*, 1 *ALB. L.J. SCI. & TECH.* 1, 3 (1991). "[O]ne of the entities that examines research proposals . . . [is] the Institutional Review Board (IRB). IRBs exist in many institutions in which research involving human subjects is performed. They are charged with the responsibil-

accomplish this by reviewing research protocols, whether directly<sup>110</sup> or indirectly.<sup>111</sup> Federal regulations require that every institution receiving a federal grant establish an IRB, with at least five people, and receive its approval before conducting human medical research.<sup>112</sup> The IRB is required to examine the protocol to weigh the risks against the benefits and determine that the researchers have communicated appropriately with the research subjects and have received their informed consent.<sup>113</sup> The federal regulations do not, however, dictate the specifics of the IRBs, leaving that to the insiders of the research community.<sup>114</sup> In the end, the reviews conducted by an IRB depend greatly on the construct and conscience of its members.<sup>115</sup>

In 1974, Congress passed the National Research Act, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, a panel that advises the government on medical ethics.<sup>116</sup> Based on the information provided by the Commission, the Department of Health, Education and Welfare (HEW)<sup>117</sup> created regulations for all federally funded medical research involving human subjects.<sup>118</sup> In 1974, the federal government adopted the Federal Policy for the Protection of Human Subjects, a joint effort of the Department of Health and Human Services and the Food and Drug Administration, often called the "Common Rule." Its purpose was to harmonize the various informal federal regulations.<sup>119</sup> These regulations included eight standards for establishing informed consent.<sup>120</sup> The gen-

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ity of reviewing, evaluating, and approving or disapproving researchers' plans to include human subjects in their investigations." *Id.* at 1.

<sup>110</sup> An example might be reviewing documents.

<sup>111</sup> An example might be community education. Moore, *supra* note 109, at 3.

<sup>112</sup> Rothman, *supra* note 6, at 41.

<sup>113</sup> *Id.* Although the established regulations only require this of research that is federally funded, there are various states and academic institutions that also require the same of research that falls within their respective jurisdictions. *Id.* at 41-42.

<sup>114</sup> *Id.* at 42.

<sup>115</sup> *Id.*

<sup>116</sup> Miller, *supra* note 46, at 210-11. The Act directed the newly created Commission to "identify the basic ethical principles [that] should underlie the conduct of biomedical and behavioral research involving human subjects." *Id.* at 211 (*citing* the National Research Act of 1974, Pub. L. No. 93-348, 88 Stat. 348 (1972) § 202(a)(1)(A)).

<sup>117</sup> The Department of Health and Human Services now administers these functions.

<sup>118</sup> Miller, *supra* note 46, at 211.

<sup>119</sup> Jonathan Moreno et al., *Updating Protections for Human Subjects Involved in Research*, 280 JAMA 1951 (1998).

<sup>120</sup> Miller, *supra* note 46, at 211. The regulation requires:

- 1) A statement that the study involves research, an explanation of the purposes of the research and the expanded duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- 2) A description of any reasonably foreseeable risks or discomforts to the subject;
- 3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

eral rules were revised in 1981 and the policy was reissued without change in 1991.<sup>101</sup> Despite the federal attempts at protecting informed consent, the Nuremberg Code has never itself been codified in federal law.<sup>102</sup>

### III. CURRENT FORCES AFFECTING RESEARCH ETHICS

#### A. FOR-PROFIT RESEARCH

The emergence of for-profit organizations conducting research has affected the allegiance to ethical principles.<sup>103</sup> Pharmaceutical companies, pushed by market forces, demand efficiency when developing new products. In addition, the entire medical system has become increasingly intertwined with the competition of economics, commerce and technology, which do not automatically act in a way that is responsive to the vulnerabilities of a research subject.<sup>104</sup> This scenario inevitably includes human trials.<sup>105</sup> In fact, human research is incredibly important to phar-

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4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8) A statement that participation is voluntary, refusal to participate will involve no penalty or no penalty or loss of benefits to which the subject is otherwise entitled. 45 C.F.R. §§ 46.116(a)(1-8)(1996).

45 C.F.R. § 46.116(a)(1-8)(1999).

In addition, the regulations require that the HHS refuse to award a federal grant for medical research unless an Institutional Review Board reviews and approves the research protocol. Miller, *supra* note 46, at 211.

<sup>101</sup> Moreno *et al.*, *supra* note 119. Very few states have regulations of this nature. Glantz, *supra* note 98, at 194. The three states that have passed statutes that regulate human medical research are California, New York and Virginia. *Id.*

<sup>102</sup> In April of 2001, the National Bioethics Advisory Commission issued a report with recommendations regarding ethical conduct of international trials. One such recommendation was to comply with the already existing informed consent requirements. There was no recommendation to either strengthen informed consent or adopt the Nuremberg Code into law. *Foreign Research Guidelines Offered*, N.Y. TIMES, Apr. 30, 2001; *Ethical and Policy Issues in Research Involving Human Participants*, at <http://www.bioethics.gov>.

<sup>103</sup> See Sean Emery & David A. Cooper, *Drug Companies Have a Duty to Continue Treatment*, 314 BRIT. MED. J. 889 (1997).

<sup>104</sup> Thomasma & Pellegrino, *supra* note 63, at xvii, xx.

<sup>105</sup> Emery & Cooper, *supra* note 122, at 889. In fact, the pharmaceutical industry claims that its sponsorship of research and development in developing nations is a benefit for those involved and that the ethics dilemma threatens the progress. *Id.* Research supports the development of infrastructure and enhances the training and experience of healthcare professionals. In return, data that define the potential clinical value of new treatments are generated. This reciprocity is threatened by problems such as the ethical dilemma. *Id.*

maceutical research; until a drug is tested on human subjects, there is no way to determine its efficacy.<sup>126</sup> It has been argued that it is an absolute necessity to continue human research. Otherwise, proponents say, there is a risk of “losing the potential benefits of new remedies, or ‘poisoning ourselves’ either with ‘insufficiently tested new remedies’ or with ‘accepted but unsound old remedies.’”<sup>127</sup> The FDA requires any drug approval to be preceded by research involving human subjects,<sup>128</sup> and the FDA faces incredible pressures of its own to facilitate the drug-approval process.<sup>129</sup> The combination of these forces creates great incentives to avoid compliance with any regulations that might hinder progress.

## B. INTERNATIONAL RESEARCH LOCATIONS

An additional factor affecting ethical principles is the current tendency to perform research in developing countries.<sup>130</sup> “Much of the research in developing countries is conducted or sponsored by the U.S. government or by pharmaceutical companies seeking product approval by the U.S. Food and Drug Administration.”<sup>131</sup> For pharmaceutical companies, it is simply less expensive to conduct research in developing countries than it is to conduct the same research in the United States or other developed countries.<sup>132</sup> The participating nations and their researchers have welcomed this realization on the part of pharmaceutical

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<sup>126</sup> Miller, *supra* note 46, at 212 (noting that products that work in test tubes or even on other animals do not always produce the equivalent result in humans).

<sup>127</sup> Verdun-Jones & Weisstub, *supra* note 78, at 91 (quoting C. FRIED, *MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY* 4 (1974)).

<sup>128</sup> Miller, *supra* note 46, at 204.

<sup>129</sup> *Id.* at 234. “The current lag time between synthesis of a new chemical entity and final FDA approval averages twelve years. It now costs an average of approximately \$231 million to take a new medicine from the laboratory to the pharmacy. Commentators blame FDA regulations for both the time delay and its attendant costs. According to them, the FDA drug-approval process prevents Americans from obtaining innovative new drug therapies in a timely manner.” *Id.*

<sup>130</sup> Troyen A. Brennan, *Proposed Revisions to the Declaration of Helsinki—Will They Weaken the Ethical Principles Underlying Human Research?*, 341 *NEW ENG. J. MED.* 527 (1999).

<sup>131</sup> *Foreign Research Guidelines Offered*, *N.Y. TIMES*, Apr. 30, 2001; David J. Rothman, *The Shame of Medical Research*, (Nov. 30, 2000), at <http://nybooks.com/nyrev/WWWfeatdisplay.cgi?20001130060f> (last visited July 30, 2001) (on file with Author) (“The attractions of conducting research in developing countries are not limited to AIDS or to academic investigators. Over the past ten years, American drug companies have been reducing their reliance upon universities to do their research, turning instead to for-profit contract-research organizations (CROs). . . . The CROs locate the research sites, recruit patients, and in some cases even draw up the study design and perform the analysis. And increasingly, the sites and patients they choose are abroad, particularly in developing countries.”) *Id.*

<sup>132</sup> Rothman, *supra* at 131. This phenomenon follows in the footsteps of other globalized industries, conducting business in the countries with the lowest costs. *Id.*

companies, having been previously excluded in the earlier research endeavors.<sup>133</sup>

#### IV. A PROPOSAL FOR CHANGE

The AIDS research conducted in Africa was particularly problematic, despite the claim that informed consent existed. Federal regulations in the United States, while attempting to protect the individual, “do not go far enough in emphasizing the centrality of the inviolability of the human rights of research subjects.”<sup>134</sup> The history of human medical research, both within the United States and U.S. funded research in other locales, glaringly shows the most dubious application of informed consent. A new standard is necessary.

Ideally, the regulations of research should fully reflect the human rights of the subjects of the medical trials,<sup>135</sup> and the underlying ethics should center around respect for the individual.<sup>136</sup> Objectification, allowing the treatment of the research subject as an end in itself rather than a means to an end, is prevented when the autonomy of the subject is respected.<sup>137</sup> The Nuremberg Code itself structures a means to secure the bodily integrity of every human involved in medical research through the doctrine of informed consent.<sup>138</sup>

This Note proposes that the United States seize the opportunity following the AIDS trials in Africa and publicly acknowledge the inadequacies of existing federal regulations. This Note urges the United States to fully and finally adopt the Nuremberg Code into law. Too many incidents involving the United States’ lack of concern for informed consent have occurred for this moment in history to pass without acknowledgement.<sup>139</sup>

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<sup>133</sup> *Id.* Previously, before the use of developing nations as research sites, the United States and Europe effectively monopolized medical research. *Id.*

<sup>134</sup> *Id.* at 24; *see also* 45 C.F.R. § 46 (providing for protection of human subjects).

<sup>135</sup> Katz, *supra* note 62, at 24. (“This will only happen, however, if it is recognized that safeguarding such rights requires not only protection from physical harm but also, and equally important, a commitment to using human beings as means for our ends only with their voluntary consent.”).

<sup>136</sup> Weisstub, *supra* note 60, at 69.

<sup>137</sup> *Id.*

<sup>138</sup> Dyckman, *supra* note 1, at 91.

<sup>139</sup> The historian Mario Biagioli in his essay on the Nazi concentration camp experiments pleaded that we need

to understand how [medical] science became (and could again become) implicated in [such a] tragedy. . . . Unless the greatest care is taken, medical science and physician-investigators are also trapped into making tragic choices for the sake of science and at the expense of human beings who serve as subjects of research. This is the eternal lesson to be learned from Auschwitz. Respect for the person is the only counterweight to such tragedies.

Katz, *supra* note 62, at 23.

Considering the controversy surrounding the AIDS trials in Africa and the inability, despite all outward professions of compliance, for the United States to follow the Nuremberg Code, the United States has an obligation to cease and desist with the current public subterfuge of claiming adherence to principles held with the Code. The Nuremberg Code, requiring real informed consent, should be accepted as the ideal and incorporated fully into federal regulations. Only then will it be possible for the practice of human medical research to hold within it the ethical principles of Nuremberg.

### CONCLUSION

The ethical assignment of assuring the respect of an individual's autonomy is not a simple task. Despite the extensive proliferation of various rules and regulations concerning human subjects of medical research, the AZT testing in Africa clearly shows that the current approach to safeguarding human rights by the United States is inadequate. Medical abuses continue to fail to treat research subjects as fully human.<sup>140</sup> The United States, despite a history of past harmful indiscretions and a publicly espoused commitment to informed consent, once again ignored the basic principles contained within the Nuremberg Code. A new standard and a new attitude must be introduced into current federal policy. A catalyst to change must be instituted that will prevent exploiting people for research by researchers who whether well or ill-meaning use their medical authoritative positions to enable their scientific research. The United States should reaffirm its commitment to individual human rights by publicly declaring allegiance to the principles within the Nuremberg Code and cease and desist from research that lacks the true and informed consent of its human research subjects.

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<sup>140</sup> Bloche, *supra* note 57, at 46.