Promising Protection through Internationally Derived Duties

Victoria Orlowski

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NOTE

Promising Protection Through Internationally Derived Duties†

Victoria Orlowskį††

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† To Eddie—whose love, strength, and bravery will inspire me forever—and to his family, whose support and kindness I’ll always cherish.
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"This legal and moral legacy promised to change the world for the better, but a good portion of that great promise has been only imperfectly realized."1

Introduction

The question of whether courts can incorporate international principles into domestic law is deeply rooted in United States jurisprudence. Critics of international law often claim that it lacks legitimacy as "law,"2 while its advocates argue that courts can freely incorporate it into the domestic legal scheme.3 This Note addresses the validity and possible implications of an instance, Grimes v. Kennedy Krieger Institute,4 where a United States court used international law to fill a gap in domestic law.

The Grimes court faced the question of whether medical researchers owe a duty of care to their subjects. With neither "federal or state statutes that mandate that all research be subject to certain conditions,"5 nor a stable body of well settled case law, the court found itself without domestic precedent.6 On the international level and in the United States, there is "virtually no enforcement of research rules" and thus no penalties for researchers who violate rules and no compensation scheme for subjects researchers violate.7

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2. This criticism stems from types of mechanisms available for enforcing international law. For a brief overview of the general enforcement mechanisms available in international law, see, for example, Frederic L. Kirgis Jr., Enforcing International Law, AM. SOC’y INT’L L. INSIGHTS, Jan. 1996, available at http://www.asil.org/insights/insight1.htm (noting the difficulty that some people have in conceptualizing law enforcement without a conventional police force to back it).
5. See id.
6. A similar situation exists on an international level, where the practice of medicine is governed by the laws of individual countries and international codes regulate human experimentation. See George J. Annas and Michael A. Grodin, Where do we go from Here?, in THE NAZI DOCTORS AND THE NUREMBERG CODE (George Annas, et. al. eds.) [hereinafter NAZI DOCTORS], at 307-14; Norman Howard-Jones, Human Experimentation, in HISTORICAL AND ETHICAL PERSPECTIVES IN HUMAN EXPERIMENTATION AND MEDICAL ETHICS 473 (Geneva: XVth CIOMS Council for International Organization of Medical Sciences Round Table Conferences) (Z. Bankowski and N. Howard Jones, eds. 1982) [hereinafter HUMAN EXPERIMENTATION].
7. Annas & Grodin, supra note 6, at 313.
Thus, the Grimes court shook the research community, by finding that a duty of care existed between researchers and their subjects. The court looked to international law to help fill gaps in federal and state law that the researchers interpreted as precluding a relationship between themselves and their subjects. The most immediate ramification of the Grimes court’s decision was its mandate that researchers rethink the ethical components of their experiments. Unlike other cases of experimentation that have rocked the research community, the Grimes court’s treatment of medical experimentation promises to provide a more lasting and useful framework for handling future cases of experimentation.

Despite existing literature focusing on the Nuremberg Code, its possible use as domestic law has received nominal attention from both courts and legal scholars. This Note attempts to fill the gap. Section one provides information on the Grimes case. Section two explains the origins and principles of the Nuremberg Code, focusing on the current problems in the research setting that the Code can help remedy. Section three examines the Code’s place in domestic law and status as customary international law. Section four demonstrates how the Nuremberg Code can be used in cases brought against American researchers by international subjects. Finally, this Note concludes that the Grimes court’s use of the Nuremberg Code—to fill gaps in domestic law in order to provide greater protection for its citizens—was proper.


9. Id. at 1 (predicting the effect of the Grimes case on the research community).

10. For examples of some of the decisions that elicited shockwaves throughout the research community, see In re Cincinnati Radiation Litigation, 874 F. Supp. 796 (S.D. Ohio 1995); PUBLIC HEALTH SERVICE, FINAL REPORT OF THE TUSKEGEE SYPHILIS STUDY AD HOC PANEL TO THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE (1973) (examining human experimentation by government doctors on African American men) [hereinafter TUSKEGEE STUDY]; JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT 1 (1993) (noting that 399 men who had disease were subjects in study); FINAL REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS (1995) (examining experiments on patients involving injection of radiation into their bodies to monitor effects) [hereinafter HUMAN RADIATION]. Despite the influence of these cases, they all settled, precluding a full resolution of the issues therein.


12. Larry I. Palmer, Disease Management and Liability in the Human Genome Era, 47 VILL. L. REV. 1, 24-28 (2002) (discussing the significance of whether courts characterize the relationship between parties as being one between a doctor/patient or researcher/subject in the “Human Genome Era”).
I. Grimes v. Kennedy Krieger Institute: Non-Therapeutic Experimentation Without Knowing Consent

In 1993 and 1994 respectively, Viola Hughes and Catina Higgins signed consent forms that effectively enrolled their children, Erika Grimes and Myron Higgins, in an experimental lead paint abatement study conducted by the Kennedy Krieger Institute (KKI). The forms the women signed apprised them of the possibility of lead poisoning in Baltimore homes, and offered them nominal compensation for their participation—five dollars for answering questions and fifteen dollars for filling out questionnaires. Under its “Benefits” section, the consent form promised that the researchers would provide the women with “blood-specific results” of their children’s lead levels, summaries of house test results, and steps that the women could take to reduce their children’s risk of lead exposure. The forms did not contain a section entitled “Risks,” did not clearly disclose that the researchers’ goal was to observe raised levels of lead in their children’s blood, and did not state that the experiment would only suc-


14. See Grimes, 782 A.2d at 820. The purpose of the study was to find an economically efficient level of lead paint abatement, in order to encourage landlords to retain low-income housing with “safe” levels of lead.


17. “We would provide you with specific blood-lead results. We would contact you to discuss a summary of house test results and steps that you could take to reduce any risks of exposure.” Id. at 825.

18. Id. For general information on lead paint disclosure requirements, see EPA Fact Sheet, EPA and HUD Move to Protect Children from Lead-Based Paint Poisoning; Disclosure of Lead-Based Paint Hazards in Housing, March 1996, available at http://www.hud.gov/offices/lead/1018/fs-discl.pdf; Protect Your Family from Lead in Your Home, supra note 15 (noting that the effects of lead include damage to the brain and nervous system, behavioral and learning problems, slowed growth, hearing problems, headaches and that children and young babies are at a higher risk because they are “more sensitive to the damaging effects of lead”).

ceed if the children stayed in the homes long enough to enable the researchers to observe noteworthy increases in the lead levels of their blood. 20

Additionally, the forms the KK1 researchers presented to the women did not reveal that their goal was to find a less than complete level of lead paint abatement or that their experiment was a utilitarian project designed to find an economically feasible way for Baltimore landlords with low cost rental units to maintain them through partial abatements rather than abandon them due to prohibitive costs of full abatement. 21 After cooperating with the researchers, the women discovered that they were not informed of their children's raised lead levels and filed suits against the researchers. 22

The lower court dismissed the women's cases on summary judgment, 23 holding that a "special-relationship" did not exist between them and the researchers. 24 However, the Maryland Court of Appeals reversed the dismissal, finding that "the very nature of non-therapeutic scientific research on human subjects can, and normally will, create special relationships out of which duties arise." 25 After this announcement, the Court immediately launched into a discussion of the Nuremberg Code. 26

United States courts have had little opportunity to address cases involving human experimentation. Within those cases few have survived to produce a final binding judgment—making it difficult for courts to

20. For information on the risks that exposure to lead paint poses to children, see sources cited supra notes 15, 18.
22. Id.; Young, supra note 13.
24. The special relationship referred to is a fiduciary relationship, like the one that exists between a doctor and his or her patient. See id. at 825. Plaintiffs must establish their cause of action in tort. The first step, which is often the hardest for experimentation subjects to meet, is the initial duty analysis. Unlike a case involving a doctor who uses experimental treatments on his patient, there is not an inherent fiduciary duty that binds a researcher to his subject. George J. Annas, Questing for Grails: Duplicity, Betrayal and Self-Deception in Postmodern Medical Research, 12 J. CONTEMP. HEALTH L. & POL’Y 297 (1996) (arguing that current research protocol blurs the patient/subject distinction). It seems that the Institutional Review Board (IRB) in Grimes recognized that the proposed research was non-therapeutic in nature and thus suggested use of language in the "informed consent" form that would make the research sound more therapeutic. See Grimes, 782 A.2d at 812-13; see also Katharine O. Adams, The Maryland Survey: 2000-2001: Recent Decisions; X. Torts, 61 Md. L. Rev. 1043 (2002) (discussing the implication of the Grimes case on tort law in Maryland, and concluding that although the case was correctly decided, it failed to adequately instruct courts on how to handle similar cases in the future); Beh, supra note 8. 25. See Grimes, 782 A.2d at 835. For recent articles on the ramifications of the court's decision, see Leonard H. Glantz, Nontherapeutic Research with Children: Grimes v. Kennedy Krieger Institute, Am. J. PUB. HEALTH, July 1, 2002; Gwendolyn Johnson, Grimes v. Kennedy Krieger Inst., Inc: The Court of Appeals of Maryland Distinguishes Special Relationships that may Arise to the Level of A Contractual Relationship between Researchers and Non-therapeutic Research Participants, U. BALT. J. ENVTL. L. (2001); Loretta M. Kopel, Pediatric Research Regulations Under Legal Scrutiny: Grimes Narrows their Interpretation, J. L. MED. & ETHICS (2002); Adams, supra note 24.
26. The Court uses the Nuremberg Code and Helsinki Declaration in addition to United States regulations. See Grimes, 782 A.2d at 849-50, 857-58, 861.
develop a "common law" of human experimentation.\textsuperscript{27} The court in \textit{Grimes} noted this lacuna in U.S. jurisprudence and turned to international law because it could not uncover domestic law that created a duty between researchers and their subjects.\textsuperscript{28} Summarily precluding the possibility of the researchers making utilitarian arguments,\textsuperscript{29} the \textit{Grimes} court drew attention to the fact that "the Nuremberg Code, at least in significant part, was the result of legal thought and legal principles, as opposed to medical or scientific principles, and thus should be the preferred standard for assessing the legality of scientific research on human subjects."\textsuperscript{30}

The Nuremberg Code's judicially crafted nature and the absence of judicial precedent reinforced the Code's weight as the "most complete and authoritative statement of the law of informed consent to human experimentation."\textsuperscript{31} The court blankly accepted the Code's applicability and weight—calling it "part of international common law" that "may be applied, in both civil and criminal cases, by state, federal and municipal courts in the United States."\textsuperscript{32} Basing its decision on the Nuremberg Code and the protections offered by federal and state laws, the \textit{Grimes} court found that the researchers and the IRB at the Kennedy Krieger Institute had a partial misperception of the difference between therapeutic and non-therapeutic research and of their own role in the process.\textsuperscript{33}

\textsuperscript{27} Many of these cases, particularly the more notorious ones, settle. Others are dismissed on summary judgment or do not receive a full consideration of relevant issues. See \textit{supra} note 10, and accompanying text.

\textsuperscript{28} \textit{Id.} at 814; see Kopel, \textit{supra} note 25 (discussing the relationship between the \textit{Grimes} decision and 45 C.F.R. § 46); \textit{c.f.} Kendall Ann Dasaulniers, \textit{Legislation to Protect the Decisionally Incapacitated Individual's Participation in Medical Research: Safety Net or Trap Door?}, 13 REGENT U. L. REV. 179, 194-214 (2000-01) (discussing Maryland's failed legislative attempts to implement its own regulations); see \textit{generally} Adams, \textit{supra} note 24.

This gap is striking considering that the United States is considered to have some of the most extensive regulation concerning medical research in the world. Curran calls U.S. regulations, "the most detailed provisions ever adopted in any country concerning informed consent and documentation of consent" William J. Curran, \textit{New Ethical-Review Policy for Clinical Medical Research}, 304 NEW ENG. J. MED. 952-54 (1988). However, United States regulations are more lax concerning who can be subjects of research than other nations. Further, despite these U.S. regulations, plaintiffs in cases involving medical research often find it difficult to survive summary judgment.

\textsuperscript{29} See \textit{Grimes}, 782 A.2d at 815-16.

\textsuperscript{30} See \textit{id.} at 835.


\textsuperscript{32} \textit{Id.}

\textsuperscript{33} \textit{Grimes}, 782 A.2d at 840. For an example of objections to the scheme of ethical review boards, see Henry K. Beecher, \textit{Ethics and Clinical Research}, 274 NEW ENG. J. MED. 1354, 1360 (1966).
The court found several problems with the KKI researchers conduct. First, the researchers previously published the results of a study that found that lead-bearing dust is particularly hazardous for children. Further the researchers recruited landlords, who typically rented to low-income families, and arranged for them to receive funds through government subsidies or loans to perform the abatement. The landlords were then encouraged or required to rent their units to families with small children. Concerning the researchers, the court noted that they "apparently saw nothing wrong" with their intention to create lead accumulations in the blood of healthy children or with their belief that the consent of the children's parents made their research appropriate.

Similarly, the Grimes court found the KKI’s IRB had a partial misperception of the difference between therapeutic and non-therapeutic research and of its role in the process—because it was willing to aid researchers in getting around federal regulations designed to protect children used as subjects in non-therapeutic research. The minutes of the IRB’s meeting alone revealed that the IRB failed to protect potential researchers’ subjects, when it suggested a change to the lead-paint abatement experiment’s proposed consent form:

The next issue has to do with drawing blood from the control population, namely children growing up in modern urban housing. Federal guidelines are really quite specific regarding using children as controls in projects in which there is no potential benefit [to the particular children]. To call a subject a normal control is to indicate that there is no real benefit to be received [by the particular children]. So we think it would be much more acceptable to indicate that the 'control group' is being studied to determine what exposure outside the home may play in a total lead exposure; thereby, indicating that these control individuals are gaining some benefit, namely learning whether safe housing alone is sufficient to keep the blood-lead levels in acceptable bounds. We suggest that you modify... consent form[s] ... accordingly.

By finding a duty on the part of both the IRB and the researchers, the Grimes court effectively opened the door to holding both groups accountable for unethical experimentation schemes.

34. *Grimes*, 782 A.2d at 812.
35. *Id.* at 812, n. 15.
36. *Id.* The negative effects of lead on children are well-recognized. See generally EPA Fact Sheet, supra note 18.
II. Origins and Principles of the Nuremberg Code

The Grimes case did not involve the typical elements that lead courts to invoke international law—it involved purely domestic litigants, did not involve any "contacts" outside of United States borders, and no state agency was directly involved in the litigation. More remarkably, there are domestic laws that cover human experimentation. The Grimes court unwittingly acknowledged that precedent did not fully support its reliance on the Code when it noted that "certain international 'codes' or 'declarations' exist (one of which is supposedly binding but has never been held as such) that, at least in theory establish standards." Further, the closest the Grimes court came to looking at the Nuremberg Code's power in domestic courts was by citing to an expert who claimed that the Code is "part of the international common law and may be applied, in both civil and criminal cases, by state, federal, and municipal courts in the United States." The Court did not acknowledge that customary international law is rarely cited and even more rarely applied, nor did it address the question of its own authority to do so as a state court. The reasoning in Grimes thus lies on tenuous ground, particularly because the Court did

39. Aspects that are typically present when international law is applied include foreign parties, international contracts, diplomats, sovereigns and alleged violations of international law. See, e.g., State v. Navarro, 659 N.W.2d 487 (Wis. App. 2003) (involving a foreign national who alleged violations of the Vienna Convention); Kerr v. Islamic Republic of Iran, 145 F.3d 580 (D.D.C. 2003) (involving issues of foreign sovereign immunity).

Death sentence cases are one of the rare instances when domestic litigants evoke international law in cases involving domestic parties, however courts have consistently refused to apply international law to avoid the death sentence. See, e.g., McGilberry v. State, 843 So. 2d 21 (Miss. 2003); Kenneth Williams, The Death Penalty: Can it be Fixed?, 51 CATH. U. L. REV. 1177 (2002); Curtis A. Bradley, The Juvenile Death Penalty and International Law, 52 DUKE L.J. 485 (2002); Paolo G. Carozza, "My Friend is a Stranger": The Death Penalty and the Global Law Commune of Human Rights, 81 TEXAS L. REV. 1031 (2003).

40. Alien Torts Claim Act (ATCA) litigation provides a demonstration of foreign contacts requirements. See, e.g., Papa v. U.S., 281 F.3d 1004 (9th Cir. 2002); Bano v. Union Carbide Corp., 273 F.3d 120 (2d Cir. 2001); Hilao v. Marcos, 103 F.3d 767 (9th Cir. 1996); Bagguley v. O'Donnell 953 F.2d 660 (D.C. Cir. 1991); De Arellano et. al., v. Weinberger, 724 F.2d 143 (D.C. Cir. 1983).

41. Note that the government funded the subsidies that some landlords received to perform the abatement procedures. Grimes, 782 A.2d at 822.

42. Arguments for the application of international law in the form of customary international law and treaties are often made by death row inmates. Courts have refused these arguments, and have not defined death penalty prohibitions as customary international law. See sources cited, supra note 39.

43. Grimes, 782 A.2d at 814.

44. Id. at 835 (citing Annas, supra note 31, at 19-21 (1991)). George Annas cites Appleman, supra note 31, at 141.


46. This is due in part to the legal disposition of the case. The court needs only to find a reason to deny summary judgment by finding a duty to inform on behalf of the researchers. See Grimes, 782 A.2d at 841-42; see also, Adams, supra note 24, at
not address how the Nuremberg Code fits into domestic law. Accordingly, analysis beyond the court's simple declaration that the Nuremberg Code is binding as the law of nations is necessary. This Note aims to begin that analysis.

As part of the larger body of Nuremberg Trials following World War II, the "Medical Case," formulated "criteria [for human experimentation] said to be widely accepted by the medical profession"—the Nuremberg Code. Officially known as The United States v. Karl Brandt, the findings in the Medical Case were not considered innovative even though—prior to the promulgation of the Nuremberg Code as part of the findings in that case—Germany was one of the only countries that regulated experimentation on humans. The Medical Case itself prompted the promulgation of the first codes on medical experimentation in the United States.

The Nuremberg Code's most basic principle is voluntary consent, its "critical masterpiece." The Nuremberg Code postulates that "voluntary consent" is the sine qua non for experiments on human subjects and requires that consent, at minimum, be competent, voluntary, informed, and comprehending. Protecting human subjects is the Nuremberg Code's paramount concern, and in that vein, it regulates research settings, investigator integrity, balancing of risks and benefits and unique problems.
of vulnerable populations. Further the Code's first principle states that each individual who initiates research experimentation is responsible for that research and that he may not delegate that responsibility with impunity.

The Nuremberg Code is the "hallmark for all subsequent discourse on the ethics of human experimentation." But, due to its judicially crafted nature the Code has persuasive legal status but is not legally binding. Although it influenced the formation of other international documents concerning medical experimentation, such as the Helsinki Declaration and the Council for International Organizations of Medical Sciences (CIOMS), the protections it offers were considered "a good code for barbarians but an unnecessary code for ordinary physician-scientists." Many current federal regulations find their basis in the Nuremberg Code. However, even though the courts in the United States have used the Nuremberg Code to set criminal and civil standards of conduct, none have used it in a criminal case and only a handful have cited it in the civil context.

There is little judicial precedent concerning human experimentation, however, the accelerated mode of current scientific and medical breakthroughs promises to bring new cases to court. Before engaging in an analysis of why the Nuremberg Code is a useful framework for experimentation on human subjects, it is necessary to understand the nature of the protections it provides.

53. See Grodin, supra note 49, at 121, 122-23; Annas et al., supra note, 31 at 139.
54. Nuremberg Code, see infra at app.
55. See Annas et al., supra note, 31 at 139.
59. See Grimes, 782 A.2d at 835.
A. The Blurred Perception of Doctor-Patient/Researcher-Subject Relationships

There is an often blurred distinction between doctor-patient/researcher-subject relationships. Doctors have legal obligations or fiduciary duties to disclose information to their patients. Researchers have no similar legal duties. In the United States, federal regulations cover the researcher-subject relationship, but do not create a direct legal duty between researchers and their subjects. Rather, federal regulations make IRBs liable for the regulation of the subject-researcher relationship.

61. George Annas argues that “in less than half a century, human experimentation has been transformed from a suspect activity into a presumptively beneficial activity. With this transformation, traditional distinctions between experimentation and therapy, subject and patient, and researcher and physician have become discouragingly blurred.” George J. Annas, The Changing Landscape of Human Experimentation Nuremberg, Helsinki, and Beyond, 2 HEALTH MATRIX 119, 119-20 (1992).

62. See generally Sheldon F. Kurtz, The Law of Informed Consent: From “Doctor is Right” to “Patient Has Rights,” 50 SYRACUSE L. REV. 1243, 1260 (2000) (concluding that there was an enormous expansion in the rights of patients to know more about their medical treatment within the last fifty years and that the American public favors this development).

63. See Palmer, supra note 12, at 24-28 (discussing doctors’ duties and arguing that researchers should have similar duties to disclose information to their research subjects).

64. See Glantz, supra note 25; see also Kopel, supra note 25, at 40-46 (discussing the Grimes holding in relation to existing federal guidelines).

65. IRBs are oversight entities. In research experiments, an IRB can be required by either federal or state regulation, or sometimes by the conditions attached to governmental grants used to fund research projects. Their primary functions are to assess the protocols of the project to determine whether the project is appropriate, the consent procedures are adequate, the methods to be employed meet proper standards, reporting requirements are sufficient, as well as the assessment of various other aspects of a research project. One of their most important objectives is the review of the potential safety and the health hazard impact of a research project on the human subjects of the experiment, especially on vulnerable subjects such as children. Their function is not to help researchers seek funding for research projects. See Grimes, 782 A.2d at 813; Beh, supra note 8 (discussing IRBs in relation to the Grimes case); Katerberg, supra note 38, at 577-79 (concluding that “the bottom line, and the general consensus . . . is that the federal regulations are flexible and leave a great deal of discretion in the hands of local IRBs on how to handle informed consent for research on children subjects.”).


66. See 45 C.F.R. § 46.109 (2001) (requiring that IRB review and approve all research activities covered by Federal Policy for the Protection of Human Subjects); see also I. Glenn Cohen, Administrative Developments: New Human Subject Research Guidelines for IRBs, 28 J. L. MED. & ETHICS 305 (2000); (discussing new guidelines and the problems they are designed to fix).
This is one reason why the Hippocratic Oath—which only applies to doctors in their capacity as such—is inapplicable as an ethical restriction on researchers.67

The absence of a duty that runs directly between researchers and their subjects is disquieting for a number of reasons. First, the fact that a person can be both a doctor and a researcher and act in those capacities separately blurs the doctor/researcher distinction. This can occur, for example, when the doctor of a terminally ill patient begins to try novel treatments, when he considers his patient has “nothing to lose”—a doctor can thus unwittingly shift between a doctor and a researcher.68 In this context, the doctor/researcher can also shift between providing therapeutic and non-therapeutic care.

This is particularly problematic because courts do not usually recognize the difficulty that lay people have in distinguishing between a doctor and a researcher or the social conditioning that people have about prospective research experimentation as being capable of yielding results that will help the “higher good.” Even people who knowingly consent to be research subjects, like people entering into contracts, are most likely overly optimistic about both the amount of harm they are subjecting themselves to and about the prospective of beneficial results the study might yield.69 The Grimes court noted that whether or not a duty exists is a factual inquiry, but that in most cases one would be present.

B. The Unwitting Self-Interest of Researchers and IRBs

While researchers work to find cures for diseases, social harms and like maladies, they often unwittingly lose sight of their subject’s best interests.70 The term “subject” itself connotes an impersonal subrogation of the person who agrees to participate in the experimentation.71 Researchers

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67. The primary thrust of the Hippocratic Oath is the obligation to benefit the patient. A problem arises here when the “subject” of experiment is not a “patient.” Grodin notes, “Alexander and Ivy confused therapeutic treatment of patients with non-therapeutic experimentation on prisoners ....” Grodin, supra note 49. For a discussion of this problem in a contemporary context, see Palmer, supra note 12 at 34 (discussing the significance of whether courts characterize the relationship as between a doctor/patient or researcher/subject in the “Human Genome Era.”).

68. See Annas, supra note 62.


70. See Annas, supra note 61, at 137-140 (noting that the terminally ill are especially vulnerable to exploitation by researchers who are often unrealistically optimistic in their expectations and believe that their subjects cannot be harmed); Gelsinger, supra note 69.

71. The dictionary defines “subject” as: one that is placed under authority or control: as a vessel (1) one subject to a monarch and governed by the monarch’s law (2) one who lives in the territory of, enjoys the protection of, and owes allegiance to a sovereign power or state. WEBSTER’S DICTIONARY 1425-26 (4th ed. 1999). See also, Kurtz, supra note 62, at n.45 (noting in the context of physician-patient relationship that
have a clear interest in downplaying the possible risks and over-inflating the possible benefits of experimentation, thus they can assume "Jekyll and Hyde" like characteristics.\textsuperscript{72} In Grimes, the court noted that the researchers at KKI, "apparently saw nothing wrong" with the fact that they intended to create lead accumulations in the blood of healthy children.\textsuperscript{73}

Application of the Nuremberg Code creates a direct duty between the researcher and his subject, and thus can be tapped to establish a duty or standard of care applicable to all medical experimenters.\textsuperscript{74} Doctors might have good reasons not to completely disclose the details of procedures or treatment, such as not discouraging the patient from undergoing necessary treatment. But similar arguments cannot be made in the context of the non-therapeutic experimentation that was present in Grimes.\textsuperscript{75}

C. The Difficulty of Distinguishing Between Therapeutic/Non-therapeutic

The "therapeutic/non-therapeutic" distinction also opens possibilities for deception because it encourages IRBS and researchers to cast their experiments as beneficial in some way because subjects are less likely to participate in research which will harm or not benefit them.\textsuperscript{76} The Grimes court found that the IRB at the Kennedy Krieger Institute had a partial misperception of the difference between therapeutic and non-therapeutic research and of its own role in the process.\textsuperscript{77} Neither the researchers nor the IRB voiced ethical concerns about their purposed research project. The IRB itself suggested an alteration of the language of the consent form to, "miscast the characteristics of the study in order to avoid the responsibility informed consent contributes to the quality of medical care because patients do between when they are part of the process rather than mere objects of it)."

\textsuperscript{72} Annas, supra note 24, at 268; see Richard S. Saver, Critical Care Research and Informed Consent, 75 N.C. L. Rev. 205, 219 (1996) (noting that researchers, however well-intentioned have motives that may differ from or be contrary to their subjects); see also JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 151 (1984) (noting that "all kinds of senseless interventions are tried in a conscious effort to cure the incurable magically through a 'wonder drug,' a novel surgical procedure, or a penetrating psychological interpretation")

\textsuperscript{73} See Grimes, 782 A.2d at 813. These same researchers previously published the results of a study that found that lead-bearing dust is particularly hazardous for children. Id. at 812.

\textsuperscript{74} Annas, et. al., supra note 3152, at 8-9.

\textsuperscript{75} It must be conceded that while the children in the KKI research studies had raised levels of lead in their blood, their situation is not unique and occurs outside the realm of experimental research. Lead-based paint poisoning in children has prompted much alarm. See, e.g., Before the Senate Committee on Health, Education, Labor, and Pensions Subcommittee on Public Health, Nov. 15, 1999 (testimony of Richard J. Jackson), available at http://www.cdc.gov/washington/testimony/ch111599.htm; Alliance to End Childhood Lead Poisoning, Global Dimensions of Lead Poisoning First International Prevention Conference Final Report, May 20, 1994) available at http://www.globaleadnet.org/pdf/ipcFULL.pdf

\textsuperscript{76} Grimes, 782 A.2d at 812. For a discussion of the difficulty of determining whether treatments are research or therapy in the context of cancer and AIDS, see Annas, supra note 61, at 128-36

\textsuperscript{77} Id at 840.
inherent in non-therapeutic research.\textsuperscript{78}

The Kennedy Krieger Institute is a sophisticated and reputable research facility. If the IRB at KKI does not understand the distinction between therapeutic and non-therapeutic experimentation or is consciously willing to stretch the language in consent forms to make clearly non-therapeutic research sound beneficial,\textsuperscript{79} then one can only wonder at the misunderstandings or stretching of language and circumstance that might occur at less sophisticated research institutions.

Another common and related miscomprehension in both research and medical settings is that "informed consent" is present if a consent form was signed.\textsuperscript{80} The term "informed consent," however, connotes more than a signature—it is supposed to memorialize an autonomous decision to participate made with full knowledge of the potential risks involved in participating. However, informed consent forms are often nominalized and "viewed as a chore and a ritual, an impersonal incantation, a hurried signing of papers."\textsuperscript{81}

Courts also make this mistake by failing to distinguish between what types of consent should be required in the research and treatment set-

\textsuperscript{78} Id. at 813-14. The Grimes court reprints the minutes of the meeting where the IRB suggested this change in the consent form:

The next issue has to do with drawing blood from the control population, namely children growing up in modern urban housing. Federal guidelines are really quite specific regarding using children as controls in projects in which there is no potential benefit [to the particular children]. To call a subject a normal control is to indicate that there is no real benefit to be received [by the particular children]... So we think it would be much more acceptable to indicate that the 'control group' is being studied to determine what exposure outside the home may play in a total lead exposure; thereby, indicating that these control individuals are gaining some benefit, namely learning whether safe housing alone is sufficient to keep the blood-lead levels in acceptable bounds. We suggest that you modify... consent form[s]... accordingly.

\textsuperscript{79} The Grimes Court found that, while the suggestion of the IRB would not make this experiment any less non-therapeutic or, less regulated, this statement evidenced two things: (1) that the IRB had a partial misperception of the difference between therapeutic and non-therapeutic research and the IRB's role in the process and (2) that the IRB was willing to aid researchers in getting around federal regulations designed to protect children used as subjects in non-therapeutic research. An IRB's primary role is to assure the safety of human research subjects—not help researchers avoid safety or health-related requirements. The IRB, in this case, misconceived, at least partially, its own role. Id at 814. For an exposition on research with children, see generally Leonard H. Glantz, Research with Children, 24 AM. J.L. & MED 213 (concluding that better and clearer rules are needed to protect both children and the integrity of research endeavors).

\textsuperscript{80} Annas & Grodin, supra note 6, at 308 (arguing that the Nuremberg Code's response "is to prohibit the objectification of the subject by requiring the subject's voluntary, competent, informed and understanding consent"). Even physicians are aware of the fact that they can capitalize on their patients' inability to understand informed consent, thus physicians can "comply with the law by making required disclosures which they believe patients do not understand." Kuritz, supra note 62; see Cathy J. Jones, Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-fulfilling Prophecy, 47 WASH. & LEE L. REV. 379, 430 (1990).

tings.\textsuperscript{82} In her article focusing on the differences between research-subject and doctor-patient relationships, Karine Morin argues:

Only a distinct and strict rule on full disclosure can protect the principle of autonomy of human research subjects by making clear that they do not place their trust in physicians to regain their health, but rather that they rely on scientific experiment to yield valuable knowledge to make their participation meaningful.\textsuperscript{83}

In other words, research subjects' interests are clearly not protected by less than full disclosure of all the risks and possibilities of danger and benefit.

The Nuremberg Code helps subvert problems inherent with informed consent because it can work in concert with federal regulations by not interfering with the particular format of informed consent while maintaining special protections that both federal and other international regulations lack. No other body of regulation or code provides a stricter rule of voluntary consent. In the United States, the closest federal regulations come to the Code's protections are in the areas of fetal and prisoner research.\textsuperscript{84}

D. The Questionable Demographics of Medical Research

In the United States the catalogue of human experimentation rests primarily in poor populations. The infamous \textit{Cincinnati Radiation Litigation}, \textit{Jewish Hospital Disease Case} and \textit{Tuskegee Syphilis study}\textsuperscript{85} all involved indigent and often minority subjects who were unaware of their status as research subjects. Researchers notoriously seek low income minorities or children as subjects.\textsuperscript{86} This was also the case in \textit{Grimes},\textsuperscript{87} where even the remuneration listed under the "Benefits" section of the consent form was

\begin{footnotesize}
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\item \textsuperscript{82} Palmer, supra note 12, at 24–28 (arguing that the amount of required disclosure is greater in the research context). The treatment/research setting is not coterminous to therapeutic/non-therapeutic distinction.
\item \textsuperscript{83} See Morin, supra note 51, at 221.
\item \textsuperscript{84} See Leonard H. Glantz, \textit{The Influence of the Nuremberg Code on U.S. Statutes and Regulations}, in \textit{Nazi Doctors}, supra note 6, at 183, 198.
\item \textsuperscript{85} See In re Cincinnati Radiation Litigation, 874 F. Supp. 796 (S.D. Ohio 1995); \textit{Tuskegee Study}, supra note 10; \textit{Jones}, supra note 10 (noting that 399 men who had disease were subjects in study); \textit{Human Radiation}, supra note 10 (examining experiments on patients involving injection of radiation into their bodies to monitor effects).
\item \textsuperscript{86} See Janet Fleetwood, \textit{Conflicts of Interest in Clinical Research: Advocating for Patient-Subjects}, 8 \textit{Widener L. Symp.} J. 105 (2001); see generally, Ryan, infra note 89 (noting that abuses of clinical trial subjects, particularly children, has plagued human research). The first tests of immunization were performed on slaves and children, for further explanation and examples, see Glantz, supra note 79, at 215–18. For a descriptive analysis on why children are particularly vulnerable research subjects, see id. at 218–44 (noting that among other problems "desperate parents of terminally ill children may be unable to protect their children in the research circumstance" id. at 244)
\item \textsuperscript{87} See \textit{Grimes}, 782 A.2d at 822; see William J. Curran, \textit{Subject Consent Requirements, in Clinical Research: An International Perspective for Industrial and Developing Countries in Human Experimentation and Medical Ethics}, 35–79.
\end{itemize}
\end{footnotesize}
targeted towards low income families.\textsuperscript{88} Proposed “benefits” included $5.00 for answering questions and allowing the researcher to sketch the home, and $15 for completing each questionnaire.\textsuperscript{89} The researchers further planned to compensate the participants with gifts, coupons for leisure activities, and “on going incentives” like food coupons in exchange for collecting the children’s blood.\textsuperscript{90} Even if the families were not in need, the small rather than large amount of remuneration might cause any person to assume that the research she is participating in is not dangerous—as she would surely expect hefty remuneration for participating in potentially hazardous experimentation or exposing her children to harm.\textsuperscript{91}

III. The Nuremberg Code’s Place in Domestic Law

A. Opposition to Treating the Nuremberg Code as Law in the United States

As early as 1952, Department of Defense lawyers spoke of the Nuremberg Code as an international sanction.\textsuperscript{92} Although Pentagon lawyers recognized the Nuremberg Code as law, researchers at Harvard University, lead by Dr. Henry Beecher, claimed the Nuremberg Code was a “legalistic document” that did not apply to researchers.\textsuperscript{93} Dr. Beecher successfully

\begin{footnotesize}
\textsuperscript{88} For an application of this principle to children in the context of lead-based paint poisoning, see CDC, \textit{Recommendations for Blood Lead Screening of Young Children Enrolled in Medicaid: Targeting a Group at High Risk}, 49 \textit{MORBIDITY \\& MORTALITY WKLTY. REP.} 1 (Feb. 2000) (finding that children aged 1–5 years enrolled in Medicaid are at increased risk for having elevated blood lead levels (BLLs)) \textit{available at} http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4914a1.htm.

\textsuperscript{89} See \textit{Grimes}, 782 A.2d at 824. Another research experiment that took place in New York City involved children between the ages of six and ten who were forced to fast for eighteen-hour periods and had blood drawn from catheters. These children were exposed to doses of the diet drug fenflouramine to help measure a hormone to their brains that may be linked to anti-social behavior. The children were offered $25 gift certificates to a popular toy store and their parents revived $100 for giving their permission for their children’s participation. Ann E. Ryan, Comment, \textit{Protecting the Rights of Pediatric Research Subjects in the International Conference on Harmonization of the Technical Requirements for Registration of Pharmaceuticals for Human Use}, 23 \textit{FORDHAM INT’L L.J.} 848, 848 (2000).

\textsuperscript{90} \textit{Grimes}, 782 A.2d at n. 34.

\textsuperscript{91} For generally known information on the effects of lead on health, see sources cited, supra note 18.


\textsuperscript{93} See Jon Harkness, et al., \textit{Laying Ethical Foundations for Clinical Research}, 79 \textit{BULL. WORLD HEALTH ORG.} 365, 365 (2001).The problem here is likely exaggerated by the fact that the Medical Case itself did not treat counts two and three of the indictment—war crimes and crimes against humanity—separately.

The counts are identical in content, except for the fact that in count two the acts which are made the basis of the charges are alleged to be committed on ‘civilian and members of the armed forces [of nations] then at War with the German Reich . . . in the exercise of belligerent control,’ whereas in count three the criminal acts are alleged to have been committed against German civilians and nationals of other countries . . . . With this distinction observed, both counts will be treated as one and discussed together.

\end{footnotesize}
requested that the Nuremberg Code be subverted for his research.\footnote{Dr. Andrew Ivy was a witness from the AMA who testified against the Nazi doctors. Ironically, many commentators argue that he performed experiments very similar to those that the Nazi doctors performed.}

Researchers such as Dr. Beecher rejected the Nuremberg Code because they concluded that it was extreme and applied only to heinous "Nazi-like" crimes.\footnote{See Beecher, supra note 33 at 1360.} Further they argued that the Code is context specific and meant to apply only to the experiments performed in concentrations camps.

However, despite their rejection of the Nuremberg Code, Dr. Beecher and his colleagues did not reject the doctrine of informed consent that the Code first espoused. Although Dr. Beecher recognized the difficulty of obtaining informed consent, he found that it is "absolutely essential to strive for it for moral, sociological, and legal reasons."\footnote{Jonathan D. Moreno, Reassessing the Influence of the Nuremberg Code on American Medical Ethics, J. CONTEMP. H. L. & POL'y 347, 349 (1997).} Opponents of the Nuremberg Code argue that the Hippocratic Oath is sufficient to assure ethical behavior and that the absolute requirement of consent is inapplicable to populations, including children, upon whom important medical research has traditionally been performed.\footnote{Contrary to the first principle of the Nuremberg Code, the voluntary consent of the human subjects is neither necessary nor sufficient for ethically and legally responsible research in the United States." Norman Frost, Waived Consent for Emergency Research, 24 AM. J. L. AND MED. 163 (1998). But see Grimes, 782 A.2d 807; White v. Paulsen, 997 F. Supp. 1380 (E.D. Wash. 1998); U.S. v. Stanley, 483 U.S. 669 (1987) (O'Connor, J., dissenting).} Thus, although researchers in Dr. Beecher's camp chose to take a limited view of the Medical Case, they strongly espoused the ethical principle at the heart of the Nuremberg Code—informed consent.\footnote{See generally, Palmer, supra note 12 at 24.}

Other commentators argue that the Nuremberg Code does not adequately provide for research in emergency situations;\footnote{For this assertion as well as descriptions of these miscast experiments, see id. at 28-29; Larry L. Palmer, The Problem of Human Experimentation, 56 Md. L. REV. 604, 604-18 (1997) (analyzing legacy of Tuskegee Study). See generally TUSKEGEE STUDY, supra note 10; (examining human experimentation by government doctors on African American men); HUMAN RADIATION, supra note 10.} because it requires the subject's consent in all circumstances. An understanding of the distinction between the treatment and research setting proves that this concern is unwarranted.\footnote{See generally, Palmer, supra note 12 at 24.}

B. Support for Treating the Nuremberg Code as the law in the United States

Scholars assert that egregious human experiments in the United States, such as the Tuskegee Study of Untreated Syphilis in the Negro Male and the Human Radiation experiments "seem to scream out for an application of the Nuremberg Code." Experts on medical experimentation further...
argue that since the United States had a preeminent role in the Code's promulgation as well as in the adjudication of the Medical Case, that "[i]f there is any country that should feel itself bound by the legal precepts of the Nuremberg Code, it is the United States." ¹⁰² However, there are few precedents for the Nuremberg Code's application and those that do exist often do not set meaningful precedence.¹⁰³ For example, both the Tuskegee and Radiation experiments were settled without full adjudication and involved government agencies rather than private individuals.¹⁰⁴

As noted above, when it was issued, the Nuremberg Code flourished in the national security department.¹⁰⁵ Its influence there persists; for example before Desert Storm special legislation was sought to subvert any necessary obligations that the Code may have created.¹⁰⁶ In contrast, the Nuremberg Code's influence was practically imperceptible in both the medical and judicial spheres until 1973.¹⁰⁷ This can partially be explained by the fact that United States courts do not typically face cases concerning medical experimentation. Beginning in 1973, an evolution occurred in the judicial recognition of the Code and has evolved to the point that now, when faced with cases of human experimentation, judges in the United States routinely refer to the Nuremberg Code.¹⁰⁸


¹⁰³. Many of these cases deal with military personnel who are treated under particular legal rules, or are settled before being fully adjudicated. See, e.g., Jaffee v. U.S., 663 F.2d 1226 (3d Cir.1981); U.S. v. Stanley, 483 U.S. 669 (1987); O'Neil v. Secretary of Navy, 76 F. Supp. 2d 641 (W.D. Pa. 1999).

¹⁰⁴. See Palmer, supra note 12, at 29.

¹⁰⁵. See Moreno, supra note 976 at 350. Moreno bases his argument on the Final Report of the President's Advisory Committee on Human Radiation Experiments, released by President Clinton on Oct. 3, 1995. Moreno was a committee member. See HUMAN RADIATION, supra note 10. After the Nuremberg judgment the Secretary of Defense issued a directive requiring that human experimentation under the Department's auspices proceed only under the dictates of the Code. See Hawk, supra note 91, at 995-97.

¹⁰⁶. The FDA granted the Department of Defense immunity from Nuremberg Code requirements, thus politically sanctioning its direct violation. See DEPARTMENTS OF DEFENSE REQUEST FOR EXEMPTION FROM INFORMED CONSENT REQUIREMENTS FOR OPERATION DESERT SHIELD AND FOOD AND DRUG ADMINISTRATION RESPONSE (Dec. 18, 1999), reprinted in, Judgment and Aftermath, supra note 47, at 94; Annas, supra note 3147 at 17; George J. Annas & Michael A. Grodin, Medical Ethics and Human Rights: Legacies of Nuremberg, 3 HOFSTRA L. & POLY SYMP. 111, 120 (1999) (citing examples of experiments for governmental purposes—including U.S. military and cold war radiation experiments and the use of investigational drugs on U.S. soldiers in the Gulf War without their consent—that directly violated the Nuremberg Code); see also William Gorge Eckhart, Essay, Nuremberg-Fifty Years: Accountability and Responsibility, 65 UMKC L. Rev.1, 12 (commenting that the accountability and responsibility required by the Nuremberg Principles are being emphasized through a "surprising source"—military doctrine)

¹⁰⁷. The first court case to invoke the Code was in 1973. See Moreno, supra note 9697, at 350.

The Code was first seen as obviously applying to the imprisoned and the oppressed persons, then to all healthy subjects, then to those who were sick but would not benefit from an experiment, and then finally to those who were sick but stood a chance of benefiting from the research participation. In fact, it was not logic that was operative in this evolution, but a growth in moral perception.

This evolution in moral perception has resulted in the emergence of a sense of legal obligation to at least mention, if not give legal weight to, the Nuremberg Code.

Strong support for the Nuremberg Code's application lies in Justice O'Connor's dissent in U.S. v. Stanley, the only case the Supreme Court has addressed involving human experimentation. In Stanley, the Supreme Court denied recovery to a military officer who claimed that he was secretly administered LSD as a part of a military experiment. The majority's rejection of the Nuremberg Code was due to the combination of the Veteran Benefits Act and the "special needs" of the United States military, rather than a rejection of the Code's principles.

Justice O'Connor's dissenting opinion in Stanley rejected the majority's proposition that service in the military creates an exemption from the individual protections provided by the Nuremberg Code. Justice O'Connor argued that:

No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case. Indeed, as Justice Brennan observes, the United States military played an instrumental role in the criminal prosecution of Nazi officials who experimented with human subjects during the Second World War, and the standards that the Nuremberg Military Tribunals developed to judge the behavior of the defendants stated that the "voluntary consent of the human subject is absolutely essential ... to satisfy moral, ethical and legal concepts." If this principle is violated the very least that society can do is to see that the victims are compensated, as best they can be, by the perpetrators. I am prepared to say that our Constitution's promise of due process of law guarantees this much.

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109. See Moreno, supra note 96 at 358.
111. Compare White v. Paulsen, 997 F. Supp. 1380, n. 2 (D.D.C. 1998). The White court worked hard to differentiate its case from Stanley, by arguing that the case did not involve "straightforward non-consensual experimentation." However, Stanley did not involve straightforward non-consensual experimentation, because the Plaintiff's consent was given when he joined the armed services and not for the specific experiment to which he was subjected. For a brief discussion of the factual situation in Stanley, see Kevin M. King, Note, A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects, STAN. J. INT'L L. 163, 163-65 (1998) (noting that Master Sergeant Stanley's situation was not unique).
112. Stanley, 483 U.S. 669.
113. See Hawk, supra note 91, at 989.
Justice O’Connor found support for the first edict of the Code in the U.S. Constitution, thus placing it higher in the hierarchy of laws than it would have if she had given it status as customary international law. This is strong support for the proposition that the Nuremberg Code had legal force in the United States prior to the Grimes court’s reliance on it. Absent the special circumstances created by military exemptions present in Stanley, Justice O’Connor’s invocation of the Nuremberg Code should be persuasive.

Following Justice O’Connor’s argument, the In Re Cincinnati Radiation Litigation court suggested that because the Medical Case was tried by American judges, constitutional due process standards must have played an implicit role in the Nuremberg Code’s promulgation. Further, in Cincinnati Radiation Litigation, the court found that “even were the Nuremberg Code not afforded precedential weight in the courts of the United States, it cannot be readily dismissed from its proper context in this case.” Along with the adoption by the Department of Defense and the National Institutes of Health, the court found at least three bases for its invocation of the Code, and declared that the Nuremberg Code is “part of the law of humanity.”

C. The Nuremberg Code’s Status as Customary International Law

It remains puzzling that commentators have not focused on the Nuremberg Code’s status as international law. The Grimes court asserts that it is “part of international common law and may be applied, in both civil and criminal cases, by state, federal and municipal courts in the United States.” However, the court simply cites a legal scholar to support this statement and that legal scholar’s assertion leads only to another legal scholar’s work that assumes the Nuremberg Code’s status as customary international law. Similarly, although scholars often assert the Nuremberg Code’s applicability as customary international law, they rarely support their analysis, and typically cite to a source discussing customary international law generally rather than performing a thorough evaluation of (1) whether the

115. See id.
116. See id.; Hinkie v. United States of America 715 F. 2d 96 (3d Cir. 1983) (dismissing on summary judgment the claims of a serviceman’s widow who claimed that her one son’s death and her other son’s birth defects were caused by radiation experiments that her husband was unknowingly exposed to during his active duty in the Army); O’Neil v. Secretary of Navy, 76 F. Supp. 2d 641 (W.D. Pa. 1999); Jaffee v. U.S., 663 F.2d 1226 (3d Cir.1981).
118. See Hawk, supra note 91, at 989.
120. See id. at 821.
121. See Hawk, supra note 91, at 989-91.
123. For an elaboration of the what constitutes customary international law, see JORDAN J. FAUST, INTERNATIONAL LAW AS LAW OF THE UNITED STATES 19 (1996).
124. See Grimes, 782 A.2d 807.
125. See id. at 835 (citing Annas, supra note 31, at 19-21 (citing in part APPLEMAN, supra note 31 at 141)); Trials I supra note 31, at 14.
Code is customary international law, and; (2) if so, how the Code can be used as law in domestic courts. Courts that cite the Nuremberg Code similarly fail to deal explicitly with the essential issue of whether the Nuremberg Code’s requirement of informed consent is part of the domestic law of the United States. This Section sets out to answer that question.

Perhaps, one reason why the Grimes court does not give great attention to its statement that the Nuremberg Code is part of the law of nations is due to the definition of customary international law, or the “law of nations.” Customary international law has been defined as “founded on common consent as well as the common sense of the world.” Similarly, Blackstone stated that: “the law of nations is a system of rules . . . established by universal consent among the civilized inhabitants of the world” and “all people.” The Nuremberg Code seemingly falls under Blackstone’s definition because it appears to have been formed by the common sense of the world and, as discussed above, United States courts have even called it “part of the law of humanity.”

Two requirements—state practice and opinio juris—must be fulfilled before anything can be considered customary international law. There is no international body that makes the determination of whether or not something is customary international law, the United Nations International Court of Justice may declare that a norm is customary international law if the case it addresses goes to that issue, but it does not publish a declaration of what is and is not customary international law. On the domestic level, courts can declare customary international law norms.

126. See Grimes, 782 A.2d at 835; Trials II, supra note 31, at 181-82; Annas et al., supra note 31, at 21. For the proposition that the Nuremberg Code, as well as other international codes on human experimentation, should be customary international law, see 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. 329, 326 (2001)
127. See Palmer, supra note 12, at 29. Grimes is an example of this in that it rests the proposition that the Nuremberg Code is customary international law based on a citation to the works of George Annas and other scholars. See Grimes, 782 A.2d at 835.
128. See id.
129. See id.
131. “Customary international law results from a general and consistent practice of states followed by the, from a sense of legal obligation.” See Restatement (Third) Foreign Relations Law §.102(2) and comment (1996).
132. See id.
133. Courts in the United States have a long history of recognizing customary international law: International law is part of our law, and must be ascertained and administered by the courts of justice of appropriate jurisdiction as often as questions of right depending upon it are duly presented for their determination . . . For this purpose, where there is no treaty controlling and no controlling executive or legislative act or judicial decision, resort must be had to the customs and usages of civilized nations, and, as evidence of these, to the works of jurists and commentators who by years of labor, research, and experience have made themselves peculiarly well acquainted with the subjects of which they treat. Such works are
The Nuremberg Code fulfills both narrow and expansive definitions of the *opinio juris* component of customary international law. *Opinio juris* is the subjective element, or “pattern of legal expectation” of customary international law. A debate exists between scholars concerning whose expectations this subjective element rests upon. The more conventional view is that it derives from the state's feeling that it is obligated. However, calling that view a “false myth perpetrated in early twentieth century,” scholars like Jordan Paust argue that “the subjective element of customary international law is to be gathered from patterns of generally shared legal expectation among humankind, not merely among State elites.” Paust argues that no other referent, including the legal actions of states or their published laws would be realistic because “all human beings recognizably participate in such a process of acceptance and the shaping of attitudes whether or not such participation is actually recognized by each individual.” This grounding in the expectations of humanity can thus provide customary international law with a real authority and strength, often making it directly authoritative in particular social contexts.

Paust’s definition makes evaluating the presence of the Nuremberg Code’s *opinio juris* almost unnecessary. It is clear that individuals believe they have a right to be free from involuntary and insufficiently informed medical human experimentation. The right to personal autonomy is an essential aspect of basic human rights. However, the Nuremberg Code meets both Paust’s and the conventional definitions of *opinio juris*.

In courts, *opinio juris* can develop in an evolutionary process, thus customary international law emerges; the Nuremberg Code follows this pattern of evolution. Although the Nuremberg Code was not cited by a court until 1973, it immediately rooted itself in the country’s administrative law via the National Institute of Health and the Defense Department. Examples of this, including that the Department of Defense took as a given that the Nuremberg Code would apply in the context of Desert Storm, support the assertion that it felt obligated to apply it. Even Dr. Beecher's vehement arguments concerning the Code's inapplicability support the assertion that it would otherwise be applied—particularly when even his...
arguments support the Code's main ethical principle. Further, when the Clinical Center of the National Institutes of Health (NIH) adopted guidelines in 1952, they explicitly relied upon the Nuremberg Code.

The Nuremberg Code also has a presence in international and domestic law to fulfill the state practice component of customary international law. The United States looks to treaties and other international agreements, domestic constitutions or legislation, executive orders, declarations, draft conventions or codes, reports, resolutions or decisions of international organizations, even testimony or affidavits as evidence of state practice. It is difficult for states to actually know how another state's law treats certain legal concepts, and practically impossible to perform a world-wide survey of how states actually apply law to certain factual situations. However, a weak state practice element does not prevent the formation of customary international law, because it ultimately rests upon the practice of all participants in the international legal process. With situations involving human rights, the analysis often goes to what countries say rather than what they actually "practice." This is one of the reasons why, when assessing whether a practice is customary international law, courts often defer to legal scholarship.

There is international evidence of Nuremberg Code's influence and acceptance in international multilateral treaties and world organizations. The Helsinki Declaration and CIOMS Guidelines were directly influenced by the Nuremberg Code. Outside the specific context of conventions relating to medicine, the International Covenant on Civil and Political Rights, one of the first and the principal human rights convention, was also directly influenced by the Nuremberg Code. Its non-derogable Article 7 was directly fashioned from the Nuremberg Code's first principle. Further, when drafting this first principle, the ICCPR's drafters rejected arguments that its second sentence was redundant, and chose to retain the language specifically relating to medical experimentation: "in particular, no one shall be subjected without his free consent to medical or scientific experimentation." As of October 10, 2003, one-hundred and fifty states

141. See Beecher, supra note 33, at 1360.
142. "The rigid safeguards observed at the NIH are based on the so-called "ten commandments" of human medical research which were adopted at the Nuremberg War Crimes trials after the atrocities performed by the Nazi doctors had been exposed." Id at 185.
143. See PAUST, supra note 122, at 34.
144. See id. at 4.
145. See id. at 3.
146. See Paquete Habana 175 U.S. 677 (1900).
147. See Moreno, supra note 96, at 351; Annas, supra note 61 (discussing the hostility physician-researchers and scientific researchers had toward the Nuremberg Code, and how this hostility fueled the promulgation of the Helsinki Declaration and the CIOMS Guidelines); King, supra note 111, at 179-84.
148. "No one shall be subjected to torture or cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." See INTERNATIONAL BILL OF HUMAN RIGHTS 13, 36 (Paul Williams, ed. 1981), available at http://www.pch.gc.ca/iddp-hrd/docs/iccpr/cn1_e.shtml. The ICCPR, forms part of the Universal Declaration of Human Rights.
were party to the declaration, and thus bound to follow the ICCPR's edicts.  

D. Applying the Code in Domestic Courts

The Grimes Court's willingness to evoke international law in a domestic case to fill a lacuna in both state and federal regulations is striking. Courts rarely evoke international law in cases with purely domestic contacts — and even more rarely evoke it in the face of international and state regulations. Even if the Nuremberg Code is deemed customary international law, additional complications exist with respect to the factual situation in Grimes. Traditionally, customary international law, or the "law of nations" applied only to states or people acting under the color of state authority. Thus, a question of the applicability of customary international law to American researchers arises. Further the law of nations is considered federal common law, thus a question arises as to whether the Grimes court, as a state court, correctly applied federal law to the situation in Grimes.

International law is part of American jurisprudence, and must be ascertained and administered by the courts of justice of appropriate jurisdiction whenever questions of right depending upon it are presented for

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150. For a general discussion of the place of customary international law in domestic courts, see Paust, supra note 122, at 19; Eric George Reeves, Note, United States v. Javino: Reconsidering the Relationship of Customary International Law to Domestic Law, 50 Wash. & Lee L. Rev. 877 (1993).  
152. Most cases attempting to use international law in a domestic context involve death penalty litigation, see cases cited supra note 39.  
their determination. Customary international law has an explicit basis in Article I, section 8, clause 10 of the Constitution. There are also several other constitutional basis, including several of the amendments (especially the Ninth Amendment), that have as one of their purposes the object to serve human rights reflected in customary international law. Although scholars have argued that state courts can apply customary international law in the same manner that they apply common law, a more accepted view is that international law should be determined or made by federal courts as though it were federal law, and their view of it should bind state courts. In fact, it is practically impossible to find an instance where a court explicitly relied only on customary international law in a case between domestic litigants in any context.

Paust asserts: "[a]lthough not widely understood, the judicial power to identify, clarify and apply customary international law in cases otherwise proper before the courts has a constitutional basis in Article II, section 2, clause 1 because the 'Laws of the United States' include the "law of nations." The Restatement Third of the Foreign Relations Law of the United States supports this argument; namely that customary international law is federal substantive law and the supreme law of the land without regard to jurisdictional competency issues.

154. See Paquete Habana 175 U.S. 677 (1900).
156. The latter view would allow appeals to the Supreme Court as involving a federal question thus giving the Supreme Court a chance to establish a nation-wide rule. See Annas, supra note 24 at 8. The Supreme Court has rarely faced human experimentation cases. But see U.S. v. Stanley 483 U.S. 669 (1987). Note that due to the involvement of the U.S. military in Stanley, it is not a true indication of how the Court might react to a case involving lay persons, such as Grimes.
157. Cases involving customary international law often come up when the case involves a foreign plaintiff bringing a cause of action under the Alien Torts Claim Act. In the domestic setting, courts have not given much credence to arguments that international law should apply. Defendants often attempt to invoke customary international law to argue against the application of the death penalty. Courts in the United States have found that prohibitions against the death penalty have not risen to the status of customary international law and have not accepted arguments that customary international law forbids that application of the death penalty. See U.S. v. Bin Laden, 126 F. Supp. 2d 290, 294 (S.D. N.Y. 2001) (citing Jamison v. Collins, 100 F. Supp. 2d 647, 766-67 (S.D. Ohio 2000)). For an extended discussion of the status of the death penalty as customary international law, see Buell v. Mitchell 274 F.3d 337, 374-76 (Ohio 2001). For a suggestion on the application of customary international law with respect to juveniles receiving the death penalty, see, for example, Servin v. State 32 P.3d 1277 (Nev. 2001) (Rose, J., concurring).
158. See PAUST, supra note 122, at 6.
159. See id. at 7.
Customary international law is directly incorporable, at least for civil sanction and jurisdictional purposes, and the judiciary has the power to identify and clarify it.\(^\text{160}\) Further, because judicial duty and responsibility are based on the constitution, “a court that refuses for some specious reason to apply international law denies its own validity.”\(^\text{161}\) Another possibility for the incorporation of customary international law is through the judiciary’s power to take judicial notice.\(^\text{162}\) Although such outlets for the adoption of customary law exist, they are rarely exercised. In the context of human experimentation, the courts are the body most likely to incorporate customary international law.

Domestic judges ultimately have the discretion as to whether and to what extent international law will play in their decisions.\(^\text{163}\) Further, the Grimes court’s strong reliance on legal scholarship concerning the applicability of the Nuremberg Code is under-girded by traditional jurisprudential treatment of customary international law.\(^\text{164}\) The Supreme Court, in Paquete Habana, stated:

> Works of jurists and commentators who by years of labor, research, and experience have made themselves peculiarly well acquainted with the subjects of which they treat. Such works are resorted to by judicial tribunals, not for the speculations of their authors concerning what the law ought to be, but for trustworthy evidence of what the law really is.\(^\text{165}\)

The Grimes court, in relying on experts on the Nuremberg Code, followed a traditional route of gleaning customary international law norms.\(^\text{166}\) It is clear that the Grimes court correctly exercised its discretion by employing customary international law in a limited way—in the duty analysis of a tort case.

As some advocates of the Nuremberg Code argue that the courts of individual countries including the United States, have “consistently proven incapable of either punishing those engaged in unlawful and unethical experimentation or compensating the victims of such experimentation.”\(^\text{167}\) Although the Grimes court’s method of empowering the Nuremberg Code as customary international law might not be as provocative as some others,\(^\text{168}\) it at least invites the real possibility of providing a forum for

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\(^{160}\) See id.

\(^{161}\) See id. at 8.

\(^{162}\) See id. at 89.

\(^{163}\) See Reeves, supra note 149 at 891.

\(^{164}\) See Paquete Habana 175 U.S. 677 (1900).

\(^{165}\) See id.

\(^{166}\) See Grimes at 835.

\(^{167}\) See Annas & Grodin, supra note 6 at 312.

\(^{168}\) M.C. Bassiouni’s proposed International Covenant on Human Experimentation, and the formation of an international tribunal with civil and criminal powers to adjudicate cases involving both therapeutic and non-therapeutic research. Id. at 811; see 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, 1641 (1981). Bassiouni’s proposed covenant was rejected by the United Nations, see George J. Annas, The Man on the Moon, Immortality, and Other Millennial Myths: The Prospects and Perils of Human Genetic Human Engineer-
cases involving human experimentation while allowing domestic jurisdictions to retain control over medical experimentation.\textsuperscript{169} Further, employing customary international law—can be faster, easier and less expensive than more radical proposals such as international medical tribunals.\textsuperscript{170}

IV. Using the Nuremberg Code to Protect Subjects Outside of U.S. Borders

Researchers often support their exploitation of subject-groups with utilitarian arguments. As explained above, Nazi doctors in the Medical Case made similar arguments. American researchers are now expanding this trend through their international research endeavors.\textsuperscript{171} As evidenced through the cases above, even the United States' regulations, which are some of the most stringent regulations regarding regulations on human experimentation in the world, fall short.

The international community has been unsuccessful in ratifying an international covenant pertaining specifically to human experimentation.\textsuperscript{172} Further, if ratified, many countries like the United States do not directly incorporate international instruments into domestic law.\textsuperscript{173} If the international community could create international regulations on human experimentation, it would not guarantee the protections to the world's populations. Customary international law can help fill this gap because, excepting conscious objectors, it applies universally without respect to whether or not a country is a signatory of or party to a convention.

The problem of vulnerable populations extends beyond the borders of the United States as researchers seek places to experiment that have lax...
regulations, and are less expensive than the United States. Nigerian families recently filed a lawsuit in a New York federal court alleging that Pfizer, the world’s largest drug manufacturer, violated international law by experimenting on their children. They contend that Pfizer violated the Nuremberg Code, U.N. human rights standards and other ethical guidelines by using their children as “human guinea pigs” in clinical trials for the antibiotic known as Trovan. Plaintiffs contend that during a 1996 meningitis epidemic, Pfizer used their children as subjects without their knowledge or consent—and failed to inform them that they could refuse the experimental treatment and receive more conventional treatments at the same sites free of charge.

The district court summarily dismissed their case on the grounds of forum non conveniens. The Second Circuit Court of Appeals reinstated their case on October 8, 2003. Applying a “clear abuse of discretion” standard, the court of appeals found that the law was not settled as to whether forum non conveniens should be granted when an adequate forum does not exist elsewhere—particularly if the plaintiff could prove that basic justice could not be obtained therein.

The Second Circuit’s reinstatement of their case opens the possibility for the plaintiffs’ case to move forward towards adjudication. The weightiest challenge facing these families is to establish that the researchers owed them a duty of care, and thus violated the law of nations. Thus, if federal courts adopt and bolster the use of the Nuremberg Code, it will enable these plaintiffs to more easily argue that their case should go to a jury for consideration. The Restatement Third of Foreign Relations Law, section 702, sets out the categories that courts have used to hold individuals liable for violations of international law regardless of state authority or color of law. These claims include: genocide, slavery, murder, torture or other cruel, inhuman, or degrading punishment, prolonged arbitrary detention,

176. See Abdullahi v. Pfizer 2003 WL 22317923 at *1 (2d Cir. Oct. 8, 2003); see, e.g., Dawn Joyce Miller, Comment, Research and Accountability: The Need for Uniform Regulation of International Pharmaceutical Drug Testing 13 PAC. INT’L L. REV. 197 (2001) (when researchers from the United States and Europe perform research in developing nations, they are largely free from such research limitations of their home countries); Todres, supra note 45, at 750 (arguing that there may be sufficient international agreement on medical experimentation to demonstrate existence of custom).
177. Under N.Y. C.P.L.R. §327 (2003), courts can dismiss a case as inconvenient after balancing several factors including the burden on New York courts, the potential hardship on the defendant, the availability of an alternative forum, the situs of the transaction at issue, the residence of the parties, location of witnesses and evidence and the substantive law governing the dispute. See Islamic Republic of Iran v. Pahlavi, 62 N.Y. 2d 474, 479 (N.Y. 1984); Blueye Navigation, Inc. v. Den Norske Bank, 658 N.Y. S.2d 9, 10 (1st Dep’t 1997).
179. See id. at 766-67.
180. See Todres, supra note 45, at 767
systematic racial discrimination, or a consistent patterns of gross violations of internationally recognized human rights. In the Medical Case, experimentation were characterized as falling under the category of inhumane or degrading punishment.

Assuming the case survived procedural and choice of law grounds, researchers might attempt to use cultural relativist claims regarding their subjects' informed consent. Cultural relativism basically espouses the belief that morals develop out of culture, therefore morals vary from country to country, but also from time period to time period. Cultural relativists would argue that it should be impermissible to insist that principals not based on a particular country's culture be implemented, such as informed consent. Thus, a possible cultural relativist claim here would be that the subjects' cultural norms mandated less than full disclosure. However, this relativist claim is clearly disproved by the Abdullahi plaintiffs' pleadings and efforts to gain relief.

Beyond cultural relativist claims, researchers might also argue that full disclosure would have created a "chilling effect" on research efforts therefore impeding potentially life-saving research. Further they could claim that they made complete disclosure and consent was given, but that they were unable to prevent communication problems that affected the subjects' full understanding.

The Nuremberg Code has the power to block these arguments because it was specifically designed to subvert similar utilitarian arguments espoused by Nazi Doctors. In other words, the Nuremberg Code's requirements of informed consent are absolute—they do not allow room for either cultural relativist or utilitarian arguments.

The tragedy is that some parents may be compelled to give their consent irregardless of the risks involved—there are people necessitous

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182. See generally, Robert D. Sloane, Outrelativizing Relativism: A Liberal Defense of the Universality of International Human Rights, 34 VAND. J. TRANSNAT'L L. 527; Guyora Binder, Cultural Relativism and Cultural Imperialism in Human Rights Law, 5 BUFFALO HUM. RTS. L. REV. 211 (1999); Ryan, supra note 89 at 885-913 (discussing research regulation for dealing with child-subject in the United States, the European Union and Japan).


185. See Todres, supra note 45, at 767-68.

186. See Annas & Grodin, supra note 6, at 312.

187. See Ruth Macklin, Universality of the Nuremberg Code, in NAZI DOCTORS supra note 6, at 240, 240-57.

188. See id.

189. In the Nigerian case the plaintiffs claim that this is not the case, because more conventional medicines were available on site that the researchers failed to inform them of—plaintiffs argue that they would have employed the more conventional medicines and thus prevented the effects the experimentation, such as their claims that their children were harmed by "low-dosing." See Abdullahi, 2003 WL 22317923 at *1-2. For a further
enough to choose the offered "benefits" experiments offer over their risks in order to get treatment for their children—which is a decision, that no one should be forced to make. Poor populations without access to medicine might become the willing subjects of human experiment in attempt to survive bacterial outbreaks, AIDS and other diseases, illnesses, and infections. Abuse of their willingness to participate—or perhaps even allowing them to participate—by denying them full disclosure that meets the Nuremberg Code’s standard of informed consent could have detrimental effects for both the subjects and their society.

Initially, the subjects will feel harmed, seek recovery and refuse to participate in further research. However, more serious ramifications can result. These situations threaten to create mistrust of modern medicine by both the subjects and their society, which in turn could shatter the trust that the people have for individual physicians and caregivers. This could prompt them to resort to self-help, alternative solutions, refuse treatment, or fail to seek treatment—all of which could be detrimental to their health. Thus, the use of the Nuremberg Code as customary international law that Grimes suggests may protect American subjects of human experimentation, as well as potential human subjects throughout the world.

Conclusion

As international law grows in volume and legitimacy, domestic courts, may become more willing to adopt its principles to fill holes and vagaries in

discussion, and proposal to add a Protocol to the ICCPR to protect international subjects of research experimentation, see King, supra note 111, at 199-206 (specifically discussing populations subject to “situational coercion” and “in need”).

190. The most notorious violations of research projects in the United States involved indigents or poor. See In re Cincinnati Radiation Litigation, 874 F. Supp. 796 (S.D. Ohio 1995); Tuskegee Study supra note 10; Jones, supra note 10; Human Radiation, supra note 10.

191. See Beecher, supra note 33 at 1360. Similar arguments have been made that prisoners can never give their fully informed consent. Further they are often induced to participate by promises of early parole or other like considerations. See Garnett, supra note 80, at 455, 477-81 (1996) (arguing that a prisoner’s capacity to choose goes to the heart of the Nuremberg Code).


193. See id. at 767.

194. Ostensibly, foreign plaintiffs would be able to sue other foreign parties in United States courts through the ATCA if the Nuremberg Code was considered customary international law by United States courts. This would ensure that plaintiffs would at least have one forum open to them. Although this is a less radical remedy than others, it would provide plaintiffs with a true chance of recovery. Compare Annas & Grodin, supra note 6, at 312-13.
domestic law, particularly where international law affords more protections than domestic law. The Grimes court rightly invoked the Nuremberg Code—even if its protections are ultimately imperfect.195

By exploring why the Nuremberg Code was unquestioningly used by the Grimes court this note hoped to strengthen the Grimes court's arguments. Giving the Nuremberg Code the full strength of customary international law will help protect subjects when researchers fail to adequately provide for their humanity. The ultimate point is not that experimentation on humans should be halted or even slowed—it is that as human beings participants in research should be accorded the dignity they are deserving of as human beings.

195. To "protect and shield humans everywhere from nonconsensual research, we must implement protections." Id. at 313.
Appendix 1: The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have the legal capacity to give consent; should be so situated as to be able to exercise the free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching to 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 and understanding and enlightened decision by the experimental subject their 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 form 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.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that anticipated results will justify the performance of the experiment.

4. The experiment should be conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations would be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required though all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experimentation seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.