



2002

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Recommended Citation

Gray, Clifton R. (2002) "Comments: The "Greater Good" ... At What Cost?: How Nontherapeutic Scientific Studies Can Now Create Viable Negligence Claims in Maryland after Grimes v. Kennedy Krieger Institute, Inc.," *University of Baltimore Law Review*: Vol. 32: Iss. 1, Article 4.

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THE "GREATER GOOD" . . . AT WHAT COST?: HOW NONTHERAPEUTIC SCIENTIFIC STUDIES CAN NOW CREATE VIABLE NEGLIGENCE CLAIMS IN MARYLAND AFTER *GRIMES v. KENNEDY KRIEGER INSTITUTE, INC.*

It is always with the best intentions that the worst work is done.
- Oscar Wilde¹

I. INTRODUCTION

Nontherapeutic research on human subjects generally has been viewed as necessary to the evolution of modern medicine.² How else, for example, could preventative vaccines prove effective, other than by injecting a healthy human subject with the vaccine and then testing the subject's response to a viral or bacterial stimuli?³ Without such research, our society might still suffer from the ravages of diseases such as polio and smallpox. Once dreaded afflictions, these diseases now seem like a thing of the past.

But while history has demonstrated that nontherapeutic research is capable of achieving positive results, history has also shown us how such research can be the basis for some of the most despicable acts ever committed in the name of science.⁴ One need only to look at such instances as Nazi experimentation and the Tuskegee Syphilis Studies⁵ to understand how easily nontherapeutic research can be

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1. OSCAR WILDE, *THE WRITINGS OF OSCAR WILDE: INTENTIONS* Vol. 6, 222 (A.R. Keller & Co. 1907).
 2. See *Grimes v. Kennedy Krieger Inst., Inc.*, 366 Md. 29, 37 n.2, 782 A.2d 807, 812 n.2 (2001). The court stated that "[n]ontherapeutic research generally utilizes subjects who are not known to have the condition the objectives of the research are designed to address, and/or is not designed to directly benefit the subjects utilized in the research, but, rather, is designed to achieve beneficial results for the public at large." *Id.* See also George J. Annas, *Mengele's Birthmark: The Nuremberg Code in United States Courts*, 7 J. CONTEMP. HEALTH L. & POL'Y 17 (1991); Teresa K. Baumann, *Proxy Consent and a National DNA Databank: An Unethical and Discriminatory Combination*, 86 IOWA L. REV. 667, 693-94 (2001).
 3. See *T.D. v. N.Y. State Office of Mental Health*, 626 N.Y.S.2d 1015, 1016 (1995) (noting that "[i]n recent years, researchers have made amazing advances in psychotropic drugs, neurobiology, genetic studies, and the like, with the promise of more to come by way of prophylactic intervention. Not all experiments can be restricted to laboratory animals.") *Id.* at 1016.
 4. See *infra* note 5 and accompanying text.
 5. See *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* 220 n.35 (George J. Annas & Michael A. Grodin eds., 1992). During the infamous Tuskegee study, poor black men with syphilis were followed for decades so that the natural course of the disease could be studied. The research subjects were told only that they had "bad

abused and twisted to meet the unethical needs of researchers. It is, therefore, important to recognize that nontherapeutic research on human subjects requires the utmost in regulation and standards. To require less would no doubt invite abuse akin to the horrors of the past.

With this in mind, the Court of Appeals of Maryland recently decided the case of *Grimes v. Kennedy Krieger Institute, Inc.*⁶ In a unanimous decision, the court severely limited the ability of researchers to pursue nontherapeutic research by recognizing that a "duty of care" may now exist between medical researchers and their subjects, and that a breach of this duty may lead to negligence under Maryland law.⁷

This Comment examines the court's reasoning in *Grimes* by exploring the different theories regarding nontherapeutic consent that arose after World War II, and commends the court for its deference to the principles established in the Nuremberg Code. Part II of this Comment addresses the numerous guidelines that have been promulgated, discussing how they have or have not been adopted in federal and state courts.⁸ Part III analyzes the court's holding, which established a "duty of care" between nontherapeutic researchers and their research subjects.⁹ Furthermore, Part III examines the court's reliance upon other jurisdictions for guidance, as this was a novel issue for the court.¹⁰ Part IV examines the innate problem with children and informed consent.¹¹ Part V explores the numerous problems involved with research oversight by Institutional Review Boards (hereinafter IRBs).¹² Part VI illustrates the inherent conflict between commercial research and proper consent.¹³ Finally, Part VII discusses why the court's deference to the principles of the Nuremberg Code, in the absence of a position by the Maryland legislature, best helps to

blood," and were never informed of their diagnosis or purpose of the study even after penicillin was discovered. *Id.*

6. 366 Md. 29, 782 A.2d 807 (2001).

7. *Id.* at 113, 782 A.2d at 858. The court stated that to establish a claim for negligence under Maryland law, a party must prove four elements: "(1) that the defendant was under a duty to protect the plaintiff from injury, (2) that the defendant breached that duty, (3) that the plaintiff suffered actual injury or loss, and (4) that the loss or injury proximately resulted from the defendant's breach of the duty." *Id.* (quoting *Rosenblatt v. Exxon*, 335 Md. 58, 76, 642 A.2d 180, 188 (1994)) (footnote omitted); *see also* *Brown v. Dermer*, 357 Md. 344, 356, 744 A.2d 47, 54 (2000); *Faya v. Almaraz*, 329 Md. 435, 448, 620 A.2d 327, 333 (1993); *Lamb v. Hopkins*, 303 Md. 236, 241, 492 A.2d 1297, 1300 (1985).

8. *See infra* notes 15-56 and accompanying text.

9. *See infra* notes 57-82 and accompanying text.

10. *See infra* notes 83-110 and accompanying text.

11. *See infra* notes 111-148 and accompanying text.

12. *See infra* notes 149-163 and accompanying text.

13. *See infra* notes 164-168 and accompanying text.

protect the individual rights and dignities of nontherapeutic research subjects.¹⁴

II. BACKGROUND

A. *Pre-World War II*

Whereas now a distinction between therapeutic and nontherapeutic research is commonly recognized, United States courts prior to World War II made no such distinction.¹⁵ This lack of distinction within our judicial system is quite understandable when one considers that at the time many researchers believed that such a distinction served no purpose.¹⁶ While there undoubtedly have been experiments throughout human history that fall into these separate categories, until World War II, "the distinction between therapeutic and nontherapeutic research did not play a major part in discussions of what research was permissible."¹⁷ Researchers were not ignorant to this distinction, however. Hippocrates himself described a decidedly nontherapeutic experiment he performed on a man with a fractured skull.¹⁸ While removing fragments of bone from the fracture, the injured man's brain was stroked so as to observe the convulsive movements on the opposite side of his body.¹⁹

Surprisingly, even with such an early documentation of a nontherapeutic experiment, it was only in the aftermath of the Nuremberg Military Tribunals, when the utter depravity of the Nazi experiments became known to the world, that a concerted effort was made to explain the boundaries of proper nontherapeutic experimentation.²⁰ What resulted became known as the Nuremberg Code.²¹

B. *Post-World War II: The Nuremberg Code*

The Nuremberg Code²² (hereinafter Code) evolved as a result of the atrocities performed in the name of science during the Holo-

14. See *infra* notes 169-174 and accompanying text.

15. See Annas, *supra* note 2, at 22.

16. See MEDICAL RESEARCH WITH CHILDREN: ETHICS, LAW, AND PRACTICE 27 (Richard H. Nicholson ed., 1986).

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.* The Doctors' Trial, which was part of the post-World War II Nuremberg trials, questioned the permissible limits of human experimentation and provided the occasion for a substantive analysis of ethical standards. See Annas, *supra* note 5, at 3-4.

21. Annas, *supra* note 5, at 3-4.

22. See Annas, *supra* note 5, at 2. Pertinent parts of the Nuremberg Code read as follows:

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 free power of choice, without the interven-

caust.²³ As it stands, the Nuremberg Code is widely considered to be the "most complete and authoritative statement of the law of in-

tion of any element of force, fraud, deceit, duress, over-reaching, 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 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.

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 or unnecessary in nature.
3. The experiment should be so 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 the anticipated results will justify the performance of the experiment.
4. The experiment should be so 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 should 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 through all stages of the experiment on 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 experiment 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 the 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.

Id.

23. Annas, *supra* note 2, at 19-21. For insight into the depravity of the Nazi experiments, one need only to examine the records of their typhus experiments. Nazi concentration camp prisoners were first injected with various experimental vaccines against typhus, and then, several weeks later, with

formed consent to human experimentation," requiring that the "informed, voluntary, competent, and understanding consent of the research subject be obtained."²⁴ The Code, in significant part, "was the result of legal thought and legal principles, as opposed to medical and scientific principles, and thus should be the preferred standard for assessing the legality of scientific research on human subjects."²⁵ It is generally regarded as the most authoritative legal and ethical document governing international research standards, as well as one of the premier human rights documents in world history.²⁶ The Code itself "demonstrates a remarkable suspicion of research with human subjects and those who perform such research."²⁷

Looking at the factual background of the Code, it would appear that the Code is directed at regulating nontherapeutic research.²⁸ After all, the Code was promulgated in response to horrific acts of needless experimentation that offered research subjects no possible direct benefit.²⁹ Thus, it appears that the Code was originally designed to "regulate pure research, which is designed to provide new knowledge but is in no way intended to benefit the subject."³⁰

Medical researchers found the Code to be unduly constrictive to their practice because "(1) it was promulgated as a human rights document by judges at a criminal trial and (2) the judges made no attempt to deal with clinical research on children, healthy volunteers, patients, or mentally-impaired people."³¹ Supporters of the Nuremberg Code have rebutted the attack by stating that "[t]he answer to the first concern is that the Code is universal; the response to the second lies in an interpretation of the Code, rather than in its abandonment. A reasonable analogy is the way we interpret the United States Constitution to apply to changes in technology."³²

But one must realize that no United States court has ever awarded damages to an injured experimental subject, or punished an experimenter, because the experimenter violated the Code.³³ In fact, the first United States court decision to cite the Nuremberg Code was decided in 1973, more than twenty-five years after announcement of the

blood from a patient with typhus. Within days nearly all of the test subjects were dead. See MEDICAL RESEARCH WITH CHILDREN, *supra* note 16, at 28.

24. Annas, *supra* note 2, at 21.

25. *Grimes v. Kennedy Kreiger Inst. Inc.*, 366 Md. 29, 74, 782 A.2d 807, 835 (2001).

26. George J. Annas, *Questing for Grails: Duplicity, Betrayal and Self-Deception in Postmodern Medical Research*, 12 J. CONTEMP. HEALTH L. & POL'Y 297, 301 (1996).

27. Leonard H. Glantz, *Law, Medicine and Socially Responsible Research: Research with Children*, 24 AM. J.L. & MED. 213, 214 (1998).

28. See Annas, *supra* note 5, at 185.

29. *Id.*

30. *Id.*

31. Annas, *supra* note 5, at 303.

32. *Id.*

33. See Annas, *supra* note 2, at 24.

Code.³⁴ One reason for this may be due to American society itself and its emphasis on progress.³⁵ While the United States has “consistently argued in [its] ethical codes that the rights and welfare of research subjects must be protected; on the other hand, [it has] consistently used perceived emergencies, both national and medical, as an excuse to jettison individual rights and welfare in human experimentation.”³⁶

Such an understanding of utilitarianism, when applied to an individual's rights regarding medical research, can quickly lead to abuse if it is believed that risks need to be taken for the “greater good” of society:

This may explain why our own use of prisoners, the institutionalized retarded, and the mentally ill to test malaria treatments during World War II was generally hailed as positive, making the war ‘everyone's war.’ Likewise, in the late 1940's and early 1950's, the testing of new polio vaccines on institutionalized mentally retarded children was considered appropriate.³⁷

Americans found the Nazi experiments to be of such an abominable nature that they thought nothing similar could happen within the United States.³⁸ What Americans failed to realize, however, is the blinding effect that the pursuit of the “greater good” can inflict on researchers.³⁹ In the nontherapeutic realm of experimentation, a researcher may often “be more concerned with advancing the state of medical knowledge — and perhaps gaining fame — than with his patient's recovery.”⁴⁰ One need only to look at the misguided aspirations of researchers in what is popularly known as the “Jewish Hospital Study” that was conducted in 1963.⁴¹ Following from that egregious

34. *Id.* (opining that “[t]his is striking because all of the judges at the Doctors' Trial were Americans, the prosecutors were American, the procedural rules followed were American, and the case itself was brought under the authority of the Military Governor of the American Zone.”); *Kaimowitz v. Mich. Dep't of Mental Health*, No. 73 Civ. 19434 AW (Mich. Cir. Ct., July 10, 1973) (unreported), reprinted in ALEXANDER D. BROOKS, LAW, PSYCHIATRY AND THE MENTAL HEALTH SYSTEM 902, 916 (1974) (holding that an involuntary detained mental patient cannot give informed consent to experimental procedures).

35. Annas, *supra* note 2, at 17.

36. *Id.*

37. *Id.* at 24.

38. *Id.*

39. See, e.g., Robert D. Mulford, Note, *Experimentation on Human Beings*, 20 STAN. L. REV. 99, 100 (1967).

40. *Id.* at 105.

41. See *id.* at 99. Two doctors injected live cancer cells into 22 debilitated patients at the Jewish Chronic Disease Hospital of Brooklyn without the patients' voluntary and informed consent. *Id.* The experiment was part of a project aimed at discovering ways to build up immunities against cancer. *Id.* It was designed to test the hypothesis that bodies racked by serious, but non-cancerous, diseases would reject the cancerous cells as swiftly as

example, it is quite probable that “an investigator who is eager to confirm some hypothesis might, in informing the subject, minimize, either consciously or unconsciously, experimental risks and uncertainties.”⁴² As is often quoted, “[t]he road to Hell is paved with good intentions.”⁴³

C. *The Declaration of Helsinki*

In 1964, the World Medical Association created its own code of ethics for research: the Declaration of Helsinki.⁴⁴ Promulgated by members of the medical profession, as opposed to the lawyers and judges who fashioned the Nuremberg Code, the Declaration of Helsinki sought to displace the Code, or at least provide a reasonable alternative to its strict confines.⁴⁵

Amended three times since its inception,⁴⁶ the Declaration’s objective is to replace the human rights-based agenda of the Nuremberg Code with a more lenient medical ethics model.⁴⁷ Unlike the Nuremberg Code, however, the Declaration of Helsinki has never been formally adopted by any court in the United States.⁴⁸

healthy bodies. *Id.* The experiment confirmed the doctors’ hypothesis. *Id.*; see also *Zelevnik v. Jewish Chronic Disease Hosp.*, 366 N.Y.S.2d 163 (N.Y. App. Div. 1975); *Application of Hyman*, 248 N.Y.S.2d 245 (N.Y. Sup. Ct. 1964), *rev’d sub nom.*, *Hyman v. Jewish Chronic Disease Hosp.*, 251 N.Y.S.2d 818 (N.Y. App. Div. 1964), 206 N.E.2d 338, 397 (N.Y. 1965).

42. Mulford, *supra* note 39, at 106.

43. This proverbial phrase originates from the late 16th century and is often incorrectly attributed to Samuel Johnson. See The Phrase Finder, *available at* <http://www.samueljohnson.com/road.html>.

44. *Grimes v. Kennedy Krieger Inst., Inc.*, 366 Md. 29, 99-100, 782 A.2d 807, 849-50 (2001). The Declaration states:

Non-therapeutic biomedical research involving human subjects
(Non-clinical biomedical research)

1. *In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and the health of that person on whom biomedical research is being carried out.*
2. The subjects should be volunteers — either healthy persons or patients for whom the experimental design is not related to the patient’s illness.
3. The investigator or the investigating team should *discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.*
4. *In research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject.*

Id. at 99-100, 782 A.2d at 850.

45. See *id.* at 99 n.39, 782 A.2d at 849 n.39.

46. *Id.* at 100, 782 A.2d at 850.

47. Annas, *supra* note 2, at 26.

48. *Grimes*, 366 Md. at 99 n.39, 782 A.2d at 849 n.39.

D. *Federal Regulations for Human Research*

While the Nuremberg Code has never been considered controlling law in any United States court decision, federal regulations have been enacted imposing standards of care that attach to federally funded or sponsored research projects that use human subjects.⁴⁹ Title 45, section 46.101(a) of the Code of Federal Regulations states that:

[t]his policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency may adopt such procedural modification as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.⁵⁰

The federal regulations detailing the proper standard of care that medical researchers must adopt in regard to human subjects also outlines the general requirements for proper informed consent in such studies.⁵¹ In exhaustive detail, section 46.116(a) of Title 45 of the Code of Federal Regulations provides eight provisions that must be followed to secure the most rudimentary informed consent.⁵² Addi-

49. See 45 C.F.R. § 46.101(a) (2001).

50. 45 C.F.R. § 46.101(a) (2001).

51. See 45 C.F.R. § 46.116 (2001) (stating that "[e]xcept as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the *legally effective informed consent* of the subject or the subject's legally authorized representative.") (emphasis added).

52. See *id.* § 46.116(a). This regulation provides that, in seeking informed consent, the following information *shall be provided* to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected 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;
- (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;

tional safeguards are also provided that relate to unforeseen risks that become manifest during the course of the research.⁵³

After close scrutiny, one realizes that the federal regulations have much in common with the Nuremberg Code. An absolute requirement of informed consent to nontherapeutic experiments clearly appears in both.⁵⁴ But unlike the Nuremberg Code, which set forth rules that applied to researchers, the federal regulations were directed at the institution that received research funds.⁵⁵ Previous regulations specifically state that "safeguarding the rights and welfare of subjects at risk . . . is primarily the responsibility of *the institution* which receives or is accountable to DHEW [Department of Health, Education, and Welfare] for the funds awarded for the support of the activity."⁵⁶

III. ANALYSIS

*Grimes v. Kennedy Krieger Inst., Inc.*⁵⁷ arose out of a study performed under the auspices of the prestigious Kennedy Krieger Institute, an institute associated with Johns Hopkins University.⁵⁸ Nontherapeutic in nature, the study was created to test the effectiveness of lead paint abatement procedures in homes,⁵⁹ procedures that could be costly.⁶⁰ The court stated that "[t]he ultimate aim of the research was to find a less than complete level of abatement that would be relatively safe, but

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- (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 loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Id.

53. See 45 C.F.R. § 46.116(b)(5) (stating, when appropriate, the research subject shall be provided with "[a] statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation. . .").
54. 45 C.F.R. § 46.116; see also Annas, *supra* note 5, at 227.
55. See Annas, *supra* note 5, at 187.
56. 45 C.F.R. § 46.102(a) (1975) (emphasis added).
57. 366 Md. 29, 782 A.2d 807 (2001).
58. *Grimes*, 366 Md. at 36, 782 A.2d at 811-12.
59. The study considered five test groups, each consisting of twenty-five houses. *Id.* at 50, 782 A.2d at 820. Three of the groups consisted of houses with a significant amount of lead dust present, each of these groups receiving assigned amounts of abatement procedures. *Id.* at 50-51, 782 A.2d at 820. A fourth group was made up of houses that at one time had lead present in the form of lead-based paint but had since received a supposedly complete abatement of lead dust. *Id.* at 51, 782 A.2d at 820. The fifth and final group consisted of modern houses that had never had the presence of lead dust. *Id.*
60. *Grimes*, 366 Md. at 48, 782 A.2d at 819.

economical, so that Baltimore landlords with lower socio-economical rental units would not abandon the units.”⁶¹

The Kennedy Krieger Institute encouraged the landlords of these homes to “rent the premises to families with young children.”⁶² Children were particularly desired to participate in the study because they tend to have a greater susceptibility to ingesting lead paint, thereby providing the researchers with clearer results as to the effectiveness of the abatement procedures.⁶³ The court stated that “[i]t [could] be argued that the researchers intended that the children be the canaries in the mines but never clearly told the parents.”⁶⁴

A. *The Duty Between Researchers and Their Subjects*

In *Crimes*, the court held that “special relationships, out of which duties arise, the breach of which can constitute negligence, can result from the relationships between researcher and research subjects.”⁶⁵ This holding, however, was not evidenced by Maryland statutes or case law.⁶⁶ In fact, the holding by the court came out of “the absence of the exercise of legislative policymaking,”⁶⁷ thereby becoming what some might term as “judicial legislation.” Presumably to preemptively rebut such an accusation, the court stated that “[t]he determination of whether a duty exists under Maryland law is the ultimate function of various policy considerations as adopted by either the Legislature,

61. *Id.* at 51, 782 A.2d at 821. The court stated that:

It appears that this study was also partially motivated . . . by the reaction of property owners in Baltimore City to the cost of lead dust abatement. The cost of full abatement of such housing at times far exceeded the monetary worth of the property – in other words, the cost of full abatement was simply too high for certain landlords to be able to afford to pay or be willing to pay.

Id. at 51-52, 782 A.2d at 821.

62. *Id.* at 36-37, 782 A.2d at 812.

63. *Id.* at 38, 782 A.2d at 812-13 (stating that “[a]pparently, it was anticipated that the children, who were the human subjects in the program, would, or at least might, accumulate lead in their blood from the dust, thus helping the researchers to determine the extent to which the various partial abatement methods worked.”). *Id.* at 38, 782 A.2d at 812-13.

64. *Id.* at 38, 782 A.2d at 813 (explaining that “[i]t was a practice in earlier years . . . for subsurface miners to rely on canaries to determine whether dangerous levels of toxic gasses were accumulating in the mines . . . When the canaries began to die, the miners knew that dangerous levels of gasses were accumulating.”). *Id.*

65. *Id.* at 94, 782 A.2d at 846.

66. *See Williams v. Baltimore*, 359 Md. 101, 145-50, 753 A.2d 41, 65-68 (2000) (noting varying concepts for what constitutes a special relationship); *Holzen v. State*, 99 Md. App. 411, 415-22, 637 A.2d 871, 872-76 (1994) (defining special relationships, but looking to other jurisdictions for guidance); *see also* RESTATEMENT (SECOND) OF TORTS §§ 314A, 315 (1965) (listing examples of relationships that create a special duty).

67. *Crimes*, 366 Md. at 93-94, 782 A.2d at 846.

or, if it has not spoken, as it has not in respect to this situation, by Maryland courts.”⁶⁸

1. Creating a “Duty” Under Maryland Law

Under Maryland law, parties can establish claims of negligence by proving four elements.⁶⁹ The elements include: “(1) that the defendant was under a duty to protect the plaintiff from injury, (2) that the defendant breached that duty, (3) that the plaintiff suffered actual injury or loss, and (4) that the loss or injury proximately resulted from the defendant’s breach of the duty.”⁷⁰

At the trial level, the circuit court granted two summary judgment motions for Kennedy Krieger.⁷¹ The court’s decision was based solely on the grounds that there was no legal duty to protect the children.⁷² In reaching its decision, the court of appeals was primarily concerned with resolving the first element of negligence: whether the Kennedy Krieger Institute was under a duty to protect the children from injury.⁷³ It was essential that the court begin its analysis at this step, because “there can be no negligence where there is no duty that is due; for negligence is the breach of some duty that one person owes to another.”⁷⁴

“Duty” in negligence has been defined as “an obligation, to which the law will give recognition and effect, to conform to a particular standard of conduct toward another.”⁷⁵ There is no clear-cut way of determining whether a duty exists, but there are a number of variables to consider.⁷⁶ As the court of appeals stated in its decision in *Faya v. Almaraz*,⁷⁷ “legal scholars have long agreed that the *seriousness* of po-

68. *Id.* at 100, 782 A.2d at 850.

69. *See supra* note 7 and accompanying text.

70. *Grimes*, 366 Md. At 85, 782 A.2d at 841 (quoting *Rosenblatt v. Exxon*, 335 Md. 58, 76, 642 A.2d 180, 188 (1994)).

71. *Id.*

72. *Id.*

73. *Id.*

74. *W.Va. Cent. R.R. Co. v. Fuller*, 96 Md. 652, 666, 54 A. 669, 671 (1903).

75. PROSSER AND KEETON ON TORTS § 53 (W. Keeton ed., 5th ed. 1984); *see also* RESTATEMENT (SECOND) OF TORTS § 4 (1965).

76. *See Tarasoff v. Regents of Univ. of California*, 551 P.2d 334, 342 (1976). The court stated that important factors to consider include:

the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant’s conduct and the injury suffered, the moral blame attached to the defendant’s conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost and prevalence of insurance for the risk involved.

Id.; *see also Biakanja v. Irving*, 320 P.2d 16, 19 (1958); *Merrill v. Buck*, 375 P.2d 304, 310 (1962).

77. 329 Md. 435, 620 A.2d 327 (1993).

tential harm, as well as its probability, contributes to a duty to prevent it.”⁷⁸ Certainly the act of exposing children to the dangers of lead contamination weighed heavily in favor of the court determining that a duty existed between the Kennedy Krieger Institute and the children participating in the research study.⁷⁹

Upon recognizing that a duty existed between the Kennedy Krieger Institute and the plaintiffs, the Court of Appeals of Maryland looked for guidance in deciding what this duty should entail.⁸⁰ The court was not completely in uncharted territory when determining what duties researchers owed their subjects.⁸¹ To help guide its decision, the court looked to an analogous case, *Whitlock v. Duke University*.⁸²

2. The *Whitlock* “Foreseeability” Precedent

Whitlock involved a research subject who suffered organic brain damage from decompression experiments.⁸³ The plaintiff was an experienced diver who signed up to participate in the study in the hope that it would further his career.⁸⁴ After signing the consent form, which informed him of the dangerous risks associated with compression and decompression experimentation, the plaintiff began to participate in the research dives.⁸⁵ Following a dive that went to a simulated depth of 2250 feet, the plaintiff began experiencing problems that he attributed to his involvement in the research study.⁸⁶ After alleging that the dives resulted in permanent organic brain damage, the plaintiff filed suit against the research institution.⁸⁷

The plaintiff in *Whitlock* based one of his claims on a negligence theory, namely that the researchers controlling the study negligently

78. *Id.* at 449, 620 A.2d at 333; *see also* *Bobo v. State*, 346 Md. 706, 714-15, 697 A.2d 1371, 1375-76 (1997) (stating that “[t]wo of the relevant factors to consider in determining whether such a duty should be recognized are ‘the nature of the harm likely to result from a failure to exercise due care, and the relationship that exists between the parties.’”) (citing *Jacques v. First Nat’l Bank*, 307 Md. 527, 534, 515 A.2d 756, 759) (1986)).

79. *See Grimes*, 366 Md. at 49, 782 A.2d at 819 (“Lead poisoning poses a distinct danger to young children. It adversely effects cognitive development, growth, and behavior. Extremely high levels have been known to result in seizures, coma, and even death.”).

80. *Grimes*, 366 Md. at 97-98, 782 A.2d at 848-49.

81. *See infra* notes 83-101 and accompanying text.

82. 637 F. Supp. 1463 (M.D.N.C. 1986), *aff’d*, 829 F.2d 1340 (4th Cir. 1987).

83. *Whitlock*, 637 F. Supp. at 1465-66 (noting that the experiment consisted of four simulated deep dives for the purpose of researching high-pressure nervous syndrome).

84. *Id.*

85. *Id.* at 1465-66 (“The informed consent form advised that the risks associated with compression were of possible lung collapse, production of fluid, hearing loss, inflammation of the ear, and sinusitis. Regarding the risks associated with decompression the form advised of the risk of decompression sickness including death, disability, and joint pain.”).

86. *Id.*

87. *Id.*

failed to inform him of the risk of organic brain damage as a result of the dives.⁸⁸ The court began its analysis by stating that “plaintiffs’ claim for negligence must succeed, if at all, on the theory that Dr. Bennett should have warned him of the danger of organic brain damage.”⁸⁹ At trial, the first issue was determining what duty a researcher owes, to a subject in a nontherapeutic experimental context.⁹⁰ Much like the court of appeals in *Grimes*, the federal district court in *Whitlock* gave deference to both the Nuremberg Code⁹¹ and Title 45 section 46 of the Code of Federal Regulations.⁹² The court concluded that the degree of required disclosure of risks regarding nontherapeutic research is higher than that in the non-experimental therapeutic context and, therefore, declined to apply the same standard in each situation.⁹³ Instead, the court found that 45 C.F.R. section 46.116(a)(2)(1985)⁹⁴ should provide the proper guidance in negligence claims involving nontherapeutic research.⁹⁵ The court explicitly recognized that a “reasonably foreseeable” standard should apply when analyzing negligence claims in the nontherapeutic context.⁹⁶

Applying this “reasonably foreseeable” standard to the facts, the court found that the researchers had a duty to inform Mr. Whitlock of all the risks that were reasonably foreseeable.⁹⁷ The issue then became “whether a risk of brain damage different from that normally associated with decompression and unique to experimental deep diving was a reasonably foreseeable risk”⁹⁸ In applying this principle, however, the court found that Whitlock failed to provide any evidence that there was a foreseeable or known risk associated with the deep diving research.⁹⁹ Therefore, it could not be concluded that organic brain damage was a reasonably foreseeable risk that the researchers were required to disclose.¹⁰⁰ Finding no issue of fact as to whether the risk of organic brain damage as a result of the dives was a reasonably foreseeable risk, the court granted summary judgment to the defendants on the negligence issue.¹⁰¹

88. *Id.* at 1469.

89. *Id.* at 1470 (stating further that “[t]his follows because the general danger of organic brain damage associated with decompression was known to Mr. Whitlock as he admitted; and the informed consent form made it clear to Mr. Whitlock that the dangers associated with decompression could not always be avoided by treatment.”).

90. *Id.*

91. See *Whitlock*, 637 F. Supp. at 1470.

92. See *id.* at 1471.

93. *Id.*

94. See *supra* note 52 and accompanying text.

95. *Whitlock*, 637 F. Supp. at 1471.

96. *Id.* at 1471 n.9.

97. *Id.* at 1472.

98. *Id.*

99. *Id.*

100. *Whitlock*, 637 F. Supp. at 1472.

101. *Id.*

3. Distinguishing *Grimes* from *Whitlock*

The court of appeals in *Grimes* was quick to point out in its analysis that, unlike the dangers that befell the plaintiff in *Whitlock*, the risks associated with the lead paint exposure were clearly foreseeable and well known to the researchers.¹⁰² The court found the two cases “clearly distinguishable”¹⁰³ since “the risks associated with exposing children to lead-based paint were not only foreseeable, but were well known by [Kennedy Krieger Institute].”¹⁰⁴ The point was made even more lucid when the court explained that “it had to have been reasonably foreseeable by [Kennedy Krieger Institute] that the children’s blood might be contaminated by lead because the extent of contamination of the blood of the children would . . . be used to measure the effectiveness of the various abatement methods.”¹⁰⁵ The court found it particularly egregious that the consent forms to the research did not directly inform the parents of the children studied that some level of lead, a decidedly harmful substance, could contaminate their children’s blood.¹⁰⁶

102. *Grimes v. Kennedy Krieger Inst., Inc.*, 366 Md. 29, 98, 782. A.2d 807, 849 (2001).

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.* The Kennedy Krieger Institute Consent Form states in relevant part:
PURPOSE OF STUDY:

As you may know, lead poisoning in children is a problem in Baltimore City and other communities across the country. Lead in paint, house dust and outside soil are major sources of lead exposure for children. Children can also be exposed to lead in drinking water and other sources. We understand that your house is going to have special repairs done in order to reduce exposure to lead in paint and dust. On a random basis, homes will receive one of two levels of repair. We are interested in finding out how well the two levels of repair work. The repairs are not intended, or expected, to completely remove exposure to lead.

We are now doing a study to learn about how well different practices work for reducing exposure to lead in paint and dust. We are asking you and over one hundred other families to allow us to test for lead in and around your homes up to 8 to 9 times over the next two years provided that your house qualifies for the full two years of study. Final eligibility will be determined after the initial testing of your home. We are also doing free blood lead testing of children aged 6 months to 7 years, up to 8 to 9 times over the next two years. We would also like you to respond to a short questionnaire every 6 months. This study is intended to monitor the effects of the repairs and is not intended to replace the regular medical care your family obtains.

BENEFITS:

To compensate you for your time answering questions and allowing us to sketch your home we will mail you a check in the amount of \$5.00. In the future we would mail you a check in the amount of \$15 each time the questionnaire is completed. The dust, soil,

4. Guidance from the Federal Regulations

Also in accordance with the *Whitlock* court, the court of appeals found guidance in the federal regulations regarding what duty of informed consent is owed to a nontherapeutic research subject.¹⁰⁷ The court found it "clear from the wording of the applicable federal regulations that this requirement of informed consent continues during the duration of the research study and applies to new or changing risks."¹⁰⁸ Therefore, in Maryland, it will generally be expected of researchers in the nontherapeutic setting to promptly tell their human subjects, before consent is given, all of the risks of the research that are reasonably foreseeable.¹⁰⁹ The court recognized that a duty of care can be created in the researcher-subject relationship, and that the duty owed can be breached if proper informed consent is not given, thereby giving rise to a viable negligence claim under Maryland law.¹¹⁰

IV. THE DILEMMA OF CHILDREN AND CONSENT IN NON-THERAPEUTIC RESEARCH

Of special significance to the *Grimes* analysis was that the subjects of the research were purposely meant to be children.¹¹¹ Because children are considered to be under legal disability, they cannot give proper informed consent.¹¹² But their parents, acting as representatives, provided the research institute with consent to perform this research on their children.¹¹³ The court of appeals clearly saw the thorny situation that this case presented. If the court was to accept the Nuremberg Code's categorical statement that the informed consent of the human subject is "essential" as true, then research on young children could not be conducted. The court was not willing to

water, and blood samples would be tested for lead at the Kennedy Krieger Institute at no charge to you. 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 57-58, 782 A.2d at 824-25.

107. *See supra* Part II.D.

108. *Grimes*, 366 Md. at 98, 782 A.2d at 849.

109. *Id.*

110. *See supra* note 7 and accompanying text.

111. *Grimes*, 366 Md. at 36-37, 782 A.2d at 812.

112. *See id.* at 113, 782 A.2d at 858; *see also* ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 236 (Urban & Schwarzenberg 2d ed., 1986). A major problem concerning proposed research on children is that "children . . . lack the legal capacity to consent. In addition, many of them, particularly the younger ones, are incapable of sufficient comprehension to meet the high standards of consent to research developed in such documents as the Nuremberg Code." *Id.*

113. LEVINE, *supra* note 112, at 236 (explaining that this kind of consent is commonly referred to as "proxy consent").

go that far, however, as it is accepted that children have benefited enormously from the biomedical and behavioral knowledge that has been acquired through properly conducted research.¹¹⁴ The issue before the court thus became “[w]hat right does a parent have to knowingly expose a child not in need of therapy to health risks or otherwise knowingly place a child in danger, even if it can be argued it is for the greater good?”¹¹⁵ Realizing that this question was fraught with “profound moral and ethical implications,”¹¹⁶ the court once again looked to prior case law that had wrestled with this dilemma.¹¹⁷

A. *Strunk v. Strunk*

The Kentucky case of *Strunk v. Strunk*¹¹⁸ did not concern substituted consent for a child, but rather, substituted consent for an incompetent twenty-seven year old adult.¹¹⁹ The incompetent adult, Jerry Strunk, had an ailing brother desperately in need of a kidney transplant.¹²⁰ This brother, Tommy Strunk, was being kept alive through artificial means that were admittedly only a temporary solution.¹²¹ With his options quickly running out, Tommy Strunk’s only chance for survival was to receive a healthy kidney from his incompetent brother, Jerry.¹²² Their parents “immediately presented the legal problem as to what, if anything, could be done by the family, especially the mother and the father to procure a transplant from Jerry to Tommy.”¹²³ Both the county court and the circuit court gave their approval for the procedure.¹²⁴ Jerry Strunk himself was represented throughout the proceedings by a guardian *ad litem*, “who . . . continually questioned the power of the state to authorize the removal of an organ from the body of an incompetent who is a ward of the state.”¹²⁵

The appeals court acknowledged that it was “fully cognizant of the fact that the question before us is unique. Insofar as we have been able to learn, no similar set of facts has come before the highest court of any of the states of this nation or the federal courts.”¹²⁶ The Court of Appeals of Kentucky did recognize that “[w]here legal disability of

114. See THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 5, at 192.

115. *Grimes*, 366 Md. 104, 782 A.2d at 852.

116. *Id.* at 104, 782 A.2d at 852.

117. *Id.* at 105-11, 782 A.2d at 853-56.

118. 445 S.W.2d 145 (Ky. 1969).

119. See *id.* at 146 (“Jerry Strunk is 27 years of age, incompetent, and through proper legal proceedings has been committed to . . . a state institution maintained for the feebleminded. He has an I.Q. of approximately 35, which corresponds with the mental age of approximately six years.”).

120. *Id.* at 145.

121. See *id.*

122. *Id.* at 146.

123. *Id.*

124. *Strunk*, 445 S.W.2d at 147 (Steinfeld, J., dissenting).

125. *Id.*

126. *Id.*

the individual is shown, the jurisdiction of the court is plenary and potent to afford whatever relief may be necessary to protect his interests and preserve his estates."¹²⁷ Applying this principle to the case before it, the Court of Appeals of Kentucky found that the lower court did have the proper authority to authorize the kidney transplant of Jerry to his brother, even though Jerry was under legal disability.¹²⁸

In a rather sharp dissent by Judge Steinfeld from the Kentucky court's holding, he expressed the same concern that would later re-surface in the majority opinion in *Grimes*.¹²⁹ Especially relevant to the Court of Appeals of Maryland's decision was Judge Steinfeld's acknowledgment of the Supreme Court case of *Prince v. Massachusetts*.¹³⁰ In *Prince*, the Supreme Court opined that "[p]arents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs out of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."¹³¹ Therefore, according to Judge Steinfeld's dissent, parents should not have legal authority to substitute their consent for that of their children in instances dealing with a child's bodily integrity.¹³²

B. Hart v. Brown

A similar legal question arose in the case of *Hart v. Brown*.¹³³ The only real difference being that in *Hart* the legal disability was due to the fact that the prospective donee was a child, not a mental incompetent.¹³⁴ The court in *Hart* upheld the giving of consent by the child's parents, but only after discussing the extensive process that the parties and the court had undertaken.¹³⁵ The court noted that:

127. *Id.* (quoting 27 AM. JUR. 2D *Equity* § 69) (currently at 27A AM. JUR. 2D *Equity* § 63 (2002)).

128. *Id.* at 149.

129. *Id.* (Steinfeld, J., dissenting) ("Apparently because of my indelible recollection of a government which, to the everlasting shame of its citizens, embarked on a program of genocide and experimentation with human bodies I have been more troubled in reaching a decision in this case than in any other.").

130. 321 U.S. 158 (1944).

131. *Prince*, 321 U.S. at 170.

132. *Strunk*, 445 S.W.2d at 151 (Steinfeld, J., dissenting); see also *Bonner v. Moran*, 126 F.2d 121 (App. D.C. 1941) (holding that a fifteen-year-old's consent in removing of a skin patch for the benefit of another was legally ineffective).

133. 289 A.2d 386 (Conn. Super. Ct. 1972).

134. *Id.* at 390.

135. See *id.* (explaining that an "investigation of [the parents'] motivation and reasoning . . . has been accomplished in this matter by the participation of a clergyman, the defendant physicians, an attorney guardian *ad litem* [sic] for the donor, the guardian *ad litem* [sic] for the donee, and, indeed, this court itself.").

[I]t would appear that the natural parents would be able to substitute their consent for that of their minor children after a close, independent and objective investigation of their motivation and reasoning There is authority in our American jurisdiction that nontherapeutic operations can be legally permitted on a minor as long as the parents or other guardians consent to the procedure.¹³⁶

The Court of Appeals of Maryland sought to differentiate the *Strunk* and *Hart* cases from the case before it by explaining that there were no safeguarding processes that occurred before the research began on the children in *Grimes*, a far cry from the protective measures discussed in *Strunk* and *Hart*.¹³⁷ The court made it clear that “[w]hat is of primary importance to be gleaned in the *Hart* and *Strunk* cases is not that the parents or guardians consented to the procedures, but that they first sought permission of the courts, and received that permission, before consenting to a nontherapeutic procedure.”¹³⁸ The court broadened the sweep of the *Grimes* decision even further when it stated that “in nontherapeutic research using children, we hold that consent of a parent alone cannot make appropriate that which is inately inappropriate.”¹³⁹

C. *T.D. v. New York State Office of Mental Health*

The case that found the most favor with the court of appeals was the New York case of *T.D. v. New York State Office of Mental Health*.¹⁴⁰ In that case, one of the issues addressed by the intermediate appellate court of New York was the reasonableness of accepting parental consent for minors to participate in nontherapeutic research that may be potentially harmful.¹⁴¹ The court stated:

We also find unacceptable the provisions that allow for consent to be obtained on behalf of minors for participation in greater than minimal risk¹⁴² non-therapeutic research from

136. *Id.*

137. *Grimes*, 366 Md. at 108, 782 A.2d at 854-55.

138. *Id.* at 108, 782 A.2d at 855 (stating that “[s]cience cannot be permitted to be the sole judge of the appropriateness of such research methods on human subjects [I]n these contested cases, the research study protocols, those of which we are aware, were not appropriate.”). *Id.* at 108, 782 A.2d at 855.

139. *Id.* at 109, 782 A.2d at 855.

140. 650 N.Y.S.2d 173 (N.Y. App. Div. 1996).

141. *Id.* at 191-92.

142. See 45 C.F.R. § 46.102(i) (2001) (“*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”) (emphasis added); see also LEVINE, *supra* note 112, at 247 (“The Commission provides examples of procedures presenting no more than minimal risk; these are routine immunization, modest changes in diet

the minor's parent or legal guardian . . . [i]t follows therefore that a parent or guardian . . . may not consent to have a child submit to painful and/or potentially life-threatening research procedures that hold no prospect of benefit for the child.¹⁴³

Following this logic, the Court of Appeals of Maryland explicitly held in *Grimes* that, "in Maryland a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject."¹⁴⁴

This holding came under quick attack and was accused of being too restrictive by numerous groups, including the Association of American Medical Colleges, the Association of American Universities, the Johns Hopkins University (of which the Kennedy Krieger Institute is an affiliate), and the University of Maryland Medical System Corporation.¹⁴⁵ Their amici curiae brief, requesting a reconsideration of the court's holding, stated that:

Under the plain terms of the Court's holding, consent to participate in health research in cases involving children and others under legal disability is, as a matter of law, unavailable whenever there is any risk of harm to the participant. The overall cost of such a rule in terms of lost advantages in medical and health knowledge (and ultimately lost opportunities to cure disease and prevent suffering and loss of life) will far outweigh the asserted advantage of protecting individual rights . . . Amici profoundly disagree with this prohibition. A rule prohibiting 'nontherapeutic research or studies in which there is any risk of injury' would prohibit virtually all medical and public health research involving children and other persons under legal disability.¹⁴⁶

On October 11, 2001, the Court of Appeals of Maryland denied this motion for reconsideration of its holding,¹⁴⁷ and in doing so clarified

or schedule, physical examination, obtaining blood and urine specimens, and developmental assessments.").

143. *T.D.*, 650 N.Y.S.2d at 191-92.

144. *Grimes*, 366 Md. at 113, 782 A.2d at 858.

145. See *Amici Curiae* Brief for the Ass'n of Am. Med. Colls., et al. *Grimes v. Kennedy Krieger Inst., Inc*, 366 Md. 29, 782 A.2d 807 (2001), available at <http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/briefs.htm> (last visited Oct. 8, 2002); see also Loretta M. Kopelman, *Pediatric Research Regulations Under Legal Scrutiny: Grimes Narrows their Interpretation*, 30 J.L. MED. & ETHICS 38, 41 (2002).

146. *Amici Curiae* Brief for the Ass'n of Am. Med. Colls. et al., *Grimes v. Kennedy Krieger Inst., Inc*, 366 Md. 29, 782 A.2d 807 (2001), available at <http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/briefs.htm> (last visited Oct. 8, 2002).

147. *Grimes*, 366 Md. at 119, 782 A.2d at 861.

its decision, stating that any risk of injury or damage means any risk *beyond* a minimal risk of harm.¹⁴⁸

V. THE FALSE SECURITY OF INSTITUTIONAL REVIEW BOARD OVERSIGHT

Another issue not lost upon the court in *Grimes* was the effectiveness of Johns Hopkins' Joint Committee on Clinical Investigation in overseeing the propriety of the research.¹⁴⁹ Acting as the Institutional Review Board (IRB)¹⁵⁰ of the study, the joint committee provided for prior group review of the protocol and risks of proposed research.¹⁵¹ IRBs have the tendency to be less than completely objective, however, because "they have a professional identification with the investigator, owe a common loyalty to their joint institution, and share, at least indirectly, in the glory (and money) that research brings."¹⁵²

The court of appeals met this difficulty head on by stating that "[t]he Institutional Review Boards, IRBs, are, primarily, in-house organs. In our view, they are not designed, generally, to be sufficiently objective in the sense that they are sufficiently concerned with the ethicality of the experiments they review as they are with the success of the experiments."¹⁵³

The court took an especially critical view when the IRB involved with the lead study, "whose primary function was to insure safety and compliance with applicable regulations, encouraged the researchers to misrepresent the purpose of the research in order to bring the study under the label of 'therapeutic' and thus under a lower safety standard of regulation."¹⁵⁴ Particularly deserving of suspicion was a

148. *Id.* at 120, 782 A.2d at 862; *see also supra* note 142 and accompanying text (defining minimal risk).

149. *See Grimes*, 366 Md. at 45, 782 A.2d at 817.

150. *Id.* at 38-39, 782 A.2d at 813. In explaining IRBs, the court stated: [they] are oversight entities within the institutional family to which an entity conducting research belongs. In research experiments, an IRB can be required in some instances by either federal or state regulation, or sometimes by the conditions attached to governmental grants that are used to fund research projects. Generally, their primary functions are to determine whether the project itself is appropriate, whether the consent procedures are adequate, whether the methods to be employed meet proper standards, whether reporting requirements are sufficient, and the assessment of various other aspects of a research project. One of the most important objectives of such review is the review of the potential safety and 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.

Id. at 39, 782 A.2d at 813.

151. *See id.*

152. Mulford, *supra* note 39, at 109.

153. *Grimes*, 366 Md. at 45, 782 A.2d at 817.

154. *Id.* at 46, 782 A.2d at 817.

letter from the IRB to the lead study's head researcher.¹⁵⁵ The letter was aimed to circumvent the federal regulations regarding children and nontherapeutic research.¹⁵⁶ Understandably, the court was not amused by this correspondence.

The history of IRBs does not, as one might at first think, have a direct link to the Nuremberg Code.¹⁵⁷ In fact, the Nuremberg Code makes no mention at all of committee or peer review; all responsibility for the rights and welfare of research subjects were placed on the individual researchers.¹⁵⁸ The growth of the IRBs took off in the 1950's and 60's, when the federal government declared that no grants would be given to institutions in support of their human research projects unless they had prior peer review.¹⁵⁹ But not all have been so fast to embrace the acceptance of the IRB as a champion of ethical research protocols.¹⁶⁰ Justice Stevens, in his dissenting opinion in *Washington v. Harper*¹⁶¹, made it clear that he was wary of what amounted to "a mock trial before an institutionally biased tribunal. . . ."¹⁶² Johns Hopkins' Joint Committee on Clinical Investigation's dubious actions in *Grimes* clearly gave credence to Justice Stevens' opinion.¹⁶³

VI. THE INHERENT CONFLICT WITH COMMERCIAL RESEARCH

One problem, of seemingly gargantuan proportions, to arise out of nontherapeutic research is the almost inevitable conflict between giving fully informed consent and the desire to complete the research study as planned. In *Grimes*, the court of appeals stated that legal protections "might additionally be warranted because of the likely conflict

155. *See id.* at 39-40, 782 A.2d at 813-14.

156. *See id.* An excerpt from the letter stated:

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 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.

Id. at 40, 782 A.2d at 814.

157. *See* ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 322 (2d ed, 1986).

158. *Id.*

159. *Id.* at 322-23.

160. *Id.* at 327.

161. 494 U.S. 210 (1990) (involving the use of psychiatric medication on mental patients without their consent).

162. *Id.* at 238 (Stevens, J., dissenting).

163. *Grimes*, 366 Md. at 45-46, 782 A.2d at 817.

of interest between the goal of the research experimenter and the health of the human subject . . . when such research is commercialized."¹⁶⁴ It is not difficult to see how a researcher who has put countless time and energy into an experiment will want to see it through its entirety, especially if there is a financial enticement to the proceedings. If a human research subject was to "withdraw from the research study prior to its completion, then the results of the study could be rendered meaningless. There is thus an inherent reason for not conveying information to subjects as it arises, that might cause the subjects to leave the research project."¹⁶⁵

The purpose of the research in *Grimes*, the court concluded, "was to determine whether there was a less expensive way than full abatement that would be cost-effective in reducing lead poisoning in children from a lower economic background."¹⁶⁶ The research itself was inextricably intertwined with the commercial interests of the city of Baltimore, a factor that the court examined with a cautious eye.¹⁶⁷ The medical profession, which supposedly puts the best interests of patients as its highest priority, cannot let commercial interests unethically taint research proceedings, thereby failing the consent guidelines expounded in *Grimes*.¹⁶⁸

VII. CONCLUSION

The holding of the Court of Appeals of Maryland in *Grimes v. Kennedy Krieger Institute, Inc.* has practically allowed viable negligence claims to arise out of a "special relationship" that exists in nontherapeutic research between researchers and their human subjects.¹⁶⁹ Basically, such a relationship gives rise to a duty of care that, if breached, would be the basis for an action in negligence.¹⁷⁰ This duty includes proper informed consent of the reasonable and foreseeable risks of participation in the nontherapeutic study.¹⁷¹ Whether there is a duty of care will be decided by the trier of fact on a case-by-case basis.¹⁷²

While the acts committed by the Nazis resulting in the Nuremberg Code did not require the Nuremberg judges to delve into the subtle nuances of the ethics of human experimentation, the Court of Appeals of Maryland had to address the less obvious issue of nontherapeutic research on children. But, by adhering to the basic principles

164. *Id.* at 101, 782 A.2d at 850.

165. *Id.* at 101, 782 A.2d at 851.

166. *Id.* at 103, 782 A.2d at 852.

167. *Id.* at 42-43, 782 A.2d 815-16.

168. See Annas, *supra* note 2, at 29-30.

169. *Grimes*, 366 Md. at 113, 782 A.2d at 858; see *supra* Part III.A.

170. *Grimes*, 366 Md. at 73-74, 782 A.2d at 834; see *supra* Part III.A.

171. *Grimes*, 366 Md. at 75-76 n.31, 782 A.2d at 835-36 n.31 (quoting Annas, *supra* note 2); see *supra* Part III.A.

172. *Grimes*, 366 Md. at 113-14, 782 A.2d at 858 (relying on *Williams v. Baltimore*, 359 Md. 101, 150, 753 A.2d 41, 68 (2000)).

of the Nuremberg Code, the court took a commendable step in safeguarding the dignity of all nontherapeutic research subjects, young or old, mentally handicapped or perfectly cognizant. The court recognized the emphasis that the Nuremberg Code placed upon "the need to protect the rights of every individual research subject, regardless of the potential value to society of a research project."¹⁷³ No researcher should have the power to dedicate a person's life to the advancement of science without that person's informed consent.

The court's holding has also effectively forbidden the ability of researchers to use children as subjects in their nontherapeutic research without prior judicial approval and oversight, if that research may in any way bear more than a minimal risk to the child.¹⁷⁴ Although strict in its approach, this aspect of the court's decision undoubtedly best protects Maryland's children from being subjected to dangerous nontherapeutic experimentation for which their parents might otherwise substitute consent. As it stands, the broad holding of *Grimes v. Kennedy Krieger Institute, Inc.* has truly put the well-being of human subjects in a nontherapeutic research setting as the researcher's top priority.

Clifton R. Gray

173. MEDICAL RESEARCH WITH CHILDREN: ETHICS, LAW, AND PRACTICE 28 (Richard H. Nicholson ed., 1986).

174. *Grimes*, 366 Md. at 113, 782 A.2d at 857-58; see *supra* Part IV.C.