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Going Beyond Parents and Institutional Review Boards in Protecting Children Involved in Nontherapeutic Research

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COMMENT

GOING BEYOND PARENTS AND INSTITUTIONAL REVIEW BOARDS IN PROTECTING CHILDREN INVOLVED IN NONTHERAPEUTIC RESEARCH

"The voluntary consent of a human subject is absolutely essential."[1]

INTRODUCTION

Since the discovery of the horrifying experiments conducted by Nazi doctors during World War II, the principle of informed consent has served as the foundation for research involving human participants.[2] Defining the scope and boundaries of informed consent has been an arduous task.[3] The task becomes even more problematic when parents are asked to consent to research participation on behalf of their children.[4] Parental permission for research carrying potential

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[1] Nuremberg Code, 1946, principle 1, reprinted in 4 ENCYCLOPEDIA OF BIOETHICS 1764 (Warren T. Reich ed., 1978) [hereinafter Nuremberg Code].

[2] *See id.*; 18th WORLD MEDICAL ASSOCIATION, DECLARATION OF HELSINKI: RECOMMENDATIONS GUIDING MEDICAL DOCTORS IN BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (1964) (revised most recently by the 41st World Medical Association in Hong Kong, September, 1989) [hereinafter DECLARATION OF HELSINKI]; NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPALS AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter BELMONT REPORT].

[3] *See* Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L. J. 7, 34 (1993).

[4] Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 807, 852 (Md. 2001) ("The issue of whether a parent can consent to the participation of her or his child in a nontherapeutic health-related study that is known to be potentially hazardous to the health of the child raises serious questions with profound moral and ethical

therapeutic benefits to children raises few moral or legal implications.[5] It is highly controversial, however, whether morality permits children to serve as research participants where there are no potential benefits to the child.[6]

In the United States, federal regulations for nontherapeutic research with children[7] require parental permission for child participation in nearly all research activities.[8] This requirement is rooted in the assumption that parents will always act in the best interests of their children.[9] This Comment argues that this assumption is invalid and exposes children to unnecessary risks. When making decisions on behalf of their children, parents are highly susceptible to conflicts of interests[10] and often lack the necessary information

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implications"). *See generally* Robert J. Katerberg, *Institutional Review Boards, Research on Children, and Informed Consent of Parents: Walking the Tightrope Between Encouraging Vital Experimentation and Protecting Subjects' Rights*, 24 J.C. & U.L. 545 (1998) (discussing the legal structure of parental permission for research with children). *See also* Lainie Friedman Ross, *Children as Research Subjects: A Proposal to Revise the Current Federal Regulations Using a Moral Framework*, 8 STAN. L. & POL'Y REV 159 (1997) (discussing the moral and legal frameworks for research involving children);.

[5] *See* Leonard H. Glantz, *Research with Children*, 24 AM. J. L. & MED. 213, 220 (1998).

[6] *See, e.g.*, William G. Bartholome, *Parents, Children, and the Moral Benefits of Research*, 6 HASTINGS CTR. REP. 44 (1976) (arguing that parents have the moral authority to give permission for their child to participate in research in order to promote their moral education); Richard A. McCormick, *Proxy Consent in the Experimentation Situation*, 18 PERSP. BIOLOGY & MED. 2 (1974) (arguing the natural law approach in which parental consent is morally valid as it is presumed to represent the child's wishes); Paul Ramsey, PATIENT AS PERSON (1970) (arguing that nontherapeutic research with children is exploitation and parental permission is not valid for such research); See Ross, *supra* note 4, for full discussion on the debate.

[7] 45 C.F.R. §§ 46.401-409 (1994).

[8] 45 C.F.R. § 46.408(b) (1994).

[9] AM. SOC'Y OF HUMAN GENETICS BD. OF DIRECTORS & AM. COLL. OF MED. GENETICS BD. OF DIRECTORS, *Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents*, 57 AM. J. HUM. GENETICS 1233, 1237 (1995) [hereinafter AM. SOC'Y OF HUMAN GENETICS]; Teresa Hughes & Mary Kay Helling, *A Case for Obtaining Informed Consent from Young Children*, 6 EARLY CHILDHOOD RESEARCH QUARTERLY 225, 227-228 (1991); Gerald P. Koocher, *Competence to Consent, in* CHILDREN'S COMPETENCE TO CONSENT 113 (G.G. Melton & M.J. Saks eds., 1983); Nancy M. P. King & Larry R. Churchill, *Ethical Principles Guiding Research on Child and Adolescent Subjects*, 15, J. INTERPERSONAL VIOLENCE, 710, 719 (2000); Lois A. Weithorn, *Children's Capacities for Participation in Treatment Decision Making, in* EMERGING ISSUES IN CHILD PSYCHIATRY AND THE LAW 23 (Elissa P. Benedek & Diane H. Schetky eds., 1985).

[10] Richard E. Redding, *Children's Competence to Provide Informed Consent for Mental Health Treatment*, 50 Wash. & Lee L. Rev. 695, 698 (1993) (citing Gerald P. Koocher, *Competence to Consent: Psychotherapy*, in CHILDREN'S COMPETENCE TO CONSENT 112, 122 (Gary S. Melton et al. eds., 1983))

to give informed consent.[11] Institutional review boards, which carry the responsibility of protecting human research participants,[12] are vulnerable to similar weaknesses.[13] Additional protective mechanisms should therefore be required to provide for a more objective and informed decision-making process for child participation in nontherapeutic research.

Part I of this Comment traces the development of ethical and legal guidelines for current informed consent procedures. Part II outlines the extent of parental authority in volunteering children for research, including legal exceptions to parental permission and possible limitations imposed on parental rights by the courts. Part III challenges the assumption that parents can and will always act in their child's best interest. Part IV argues that institutional review boards cannot be relied upon to protect children when parents fail to do so. Finally, Part V proposes possible improvements to the problematic evaluation process of parents and institutions when making decisions on behalf of children.

I. BACKGROUND

A. DEVELOPMENT OF ETHICAL GUIDELINES FOR INFORMED CONSENT OF CHILDREN IN RESEARCH

In the aftermath of World War II, the Allied Powers established an international military tribunal[14] with the power

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[11] *See, e.g.*, Marilyn T. Baker & Harvey A. Taub, *Readability of Informed Consent Forms for Research in a Veterans Administration Medical Center*, 250 JAMA 2646; T. M. Grundner, *On the Readability of Surgical Consent Forms*, 302 N. ENG. J. MED. 900; Kenneth J. Tarnowski, et al., *Readability of Pediatric Biomedical Research Informed Consent Forms*, 85 PEDIATRICS 58 (1990) (studies demonstrating the lack of participant comprehension of informed consent forms).

[12] 45 C.F.R. § 46.103.

[13] *See* Dale L. Moore, *Recurrent Issues in the Review of Medical Research on Human Subjects*, 1 ALB. L. J. SCI. & TECH. 1, 12 (1991) (discussing conflicts of interest faced by IRBs); Ivor A. Pritchard, *Travelers and Trolls: Practitioner Research and Institutional Review Boards*, 31 EDUC. RESEARCHER 3, 8 (2002) (IRBs may lack the "informed understanding necessary to judge a research project fairly."); Kathryn A. Tuthill, *Protecting Patient Autonomy Through Informed Consent*, 18 J. LEGAL MED. 221, 233 (1997) (discussing conflicts of interest faced by IRBs).

[14] *Judgment of the International Military Tribunal for the Trial of German Major War Criminals at* http://www.yale.edu/lawweb/avalon/imt/proc/judgen.htm (last modified Nov. 6, 2002). The tribunal was established by agreement between the governments of the United States of America, United Kingdom of Great Britain, French Republic, and Soviet Socialist Republics. *Id.* In addition, the governments of

to try and punish war criminals.[15] The 1947 conviction of Nazi doctors for crimes against humanity gave rise to the first ethical guidelines addressing the principle of informed consent in human research.[16] The tribunal, in response to the experiments conducted in German concentration camps involving "brutalities, tortures, disabling injury, and death," under conditions contrary to "the principles of the law of nations as they result from the usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience," laid down essential principles to be observed while conducting scientific research with human subjects.[17] The ten principles enumerated in the judgment were called the Nuremberg Code and became the international standard used in later ethical and legal codes.[18]

The first and most explicit principle of the Nuremberg Code (hereinafter "Code") declares, "voluntary consent of the human subject is absolutely essential."[19] The Code states that the person "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."[20] Effective informed consent should be ensured by informing the participant of the nature, duration, purpose, method, and all risks or inconveniences that may be expected from participation in the study.[21] A requirement of "voluntary consent" includes the participant's "legal capacity to give

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Greece, Denmark, Yugoslavia, the Netherlands, Czechoslovakia, Poland, Belgium, Ethiopa, Australia, Honduras, Norway, Panama, Luxemberg, Haiti, New Zealand, India, Venezuela, Uruguay, and Paraguay expressed their adherence to the agreement. *Id.*

15 *Id.*

16 Jay Katz, *The Nuremberg Code and the Nuremberg Trial: A Reappraisal*, 276, JAMA, 1662, 1662 (1996).

17 Nuremberg Code, *supra* note 1.

18 *See* George J. Annas, *Mengele's Birthmark: The Nuremberg Code in United States Courts*, 7 J. CONTEMP. HEALTH L. & POL'Y 17, 21 (1991) (stating that the Nuremberg Code is the authoritative statement of informed consent and plays an important role in both international common law and United States court decisions.); GERALD P. KOOCHER & PATRICIA KEITH-SPIEGEL, ETHICS IN PSYCHOLOGY: PROFESSIONAL STANDARDS AND CASES 417 (1998); Nathaniel S. Lehrman & Vera Hassner Sharav, *Ethical Problems in Psychiatric Research*, 24 J. MENTAL HEALTH ADMIN. 227, 249 (1997).

19 Nuremberg Code, *supra* note 1.

20 *Id.*

21 *Id.*

consent."[22] As children were not legally competent to provide consent on their own behalf, failure to provide for any form of proxy consent[23] implied that research on children was entirely prohibited by the Code's ethical principles.[24] Although the first draft of the Code permitted consent involving incompetent persons, it was dropped from the final version.[25] The tribunal most likely chose to exclude the provisions regarding consent of incompetent persons because they did not specifically apply to the cases involved at the Nuremberg trial.[26] This apparent exclusion of children, as incompetent persons, from scientific research, as well as the Code's status as a response to the extraordinary Nazi atrocities, drew heavy criticism from the medical and scientific community.[27] Many physicians and researchers viewed the Code as applicable only to "barbarians and not for civilized physician-investigators."[28] The resulting controversy instigated an attempt by the international medical community to integrate the Code's principles into a set of research guidelines that would be more practical and relevant to the realities of scientific research.[29]

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[22] *Id.*

[23] *Id.*

[24] Ross, *supra* note 4, at 159 (stating that the omission of proxy consent from the Nuremberg Code implied that children who could not provide informed consent could not participate in medical research); Ann E. Ryan, *Protecting the Rights of Pediatric Research Subjects in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use*, 23 FORDHAM INT'L L.J. 848, 867 (2000) (stating that a weakness of the Nuremberg Code is that it "fails to provide for conducting research on subjects who are incapable of providing legal informed consent.").

[25] GERALD P. KOOCHER & PATRICIA KEITH-SPIEGEL, CHILDREN, ETHICS, & THE LAW 105 (1990) (citing L. Alexander, *Psychiatry: Methods and Processes for Investigation of Drugs*, ANNALS ACAD. SCI. 169, 347-351 (1970)).

[26] *Id.*

[27] *See generally* Ruth R. Faden, Susan E. Lederer & Jonathan D. Moreno, *US Medical Researchers, the Nuremberg Doctors Trial, and the Nuremberg Code: A Review of Findings of the Advisory Committee on Human Radiation Experiments*, 276 JAMA 1667 (1996) (discussing the criticisms of and disagreements with the Nuremberg Code that developed in the scientific community during the 1950's).

[28] Katz, *supra* note 16, at 1662-1663 (explaining that the lack of justification by the Nazi physicians for the brutal methods in research, as well as the lack of clarity as to the applicability of the code, led the Western medical community to dismiss the Code's relevancy to themselves); s*ee also* Ryan, *supra* note 24, at 867-868 (explaining that the limitations imposed by the Code invoked criticisms by the medical community who felt that the atrocities addressed during the Nuremberg Trial were irrelevant to their scientific research).

[29] *See* Annas, *supra* note 18, at 24 (explaining that the medical community saw the Code as applying to the type of experiments performed by the Nazis and that the

In 1964, the World Medical Association established a medical ethics model for biomedical research in the Declaration of Helsinki, which was adopted by the international community, including the United States.[30] The Declaration of Helsinki (hereinafter "Declaration") differed from the Nuremberg Code in several ways. First, although informed consent was included in the document,[31] it lacked the stringent requirements and the detail that it had been assigned in the Code.[32] Secondly, the Declaration, unlike the Code, distinguished therapeutic research[33] and research that was purely scientific or nontherapeutic.[34] While the aim of therapeutic research is to provide some curative benefit to the patient, nontherapeutic research is purely scientific in nature.[35] Most significant to pediatric research, the Declaration differed from the Code in that it provided for third party permission by a legal guardian for research conducted on minor children.[36] Further, in addition to parental permission, the Declaration required consent to be obtained from minors capable of giving consent.[37] Researchers in the United States, including the American Medical Association, ardently endorsed

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community's view of the Code as irrelevant to their own therapeutic experiments led to the development of the World Medical Association's Declaration of Helsinki.); Faden, Lederer & Moreno, *supra* note 27, at 1670 (stating that the international medical community attempted to bring the Nuremberg Code in line with medical research); Ryan, *supra* note 24, at 869 (stating that criticisms of the Nuremberg Code led the international community to acknowledge the necessity for practical guidelines).

30 DECLARATION OF HELSINKI, *supra* note 2.

31 DECLARATION OF HELSINKI, *supra* note 2, at Article I, 9-11.

32 Katz, *supra* note 16, at 1665 (arguing that the question of the quality of informed consent as presented in the Declaration of Helsinki was "ambiguous, confusing, and surely not as stringent as that articulated in the Nuremberg Code."); *see also* DECLARATION OF HELSINKI, *supra* note 2; Nuremberg Code, *supra* note 1.

33 DECLARATION OF HELSINKI, *supra* note 2, at Article II (labeling therapeutic research as "clinical research").

34 DECLARATION OF HELSINKI, *supra* note 2, at Article III (labeling nontherapeutic research as "non-clinical biomedical research").

35 DECLARATION OF HELSINKI, *supra* note 2, at Introduction.

36 DECLARATION OF HELSINKI, *supra* note 2, at Article I, 11. The Declaration of Helsinki states, "[i]n case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation." *Id.*

37 DECLARATION OF HELSINKI, *supra* note 2, at Article I, 11. The Declaration of Helsinki states, "[w]henever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian." *Id.*

the Declaration, as it provided a more practical and realistic approach to the research setting.[38] Despite its widespread approval, evidence of abuse in scientific research during the 1960's made it apparent that the Declaration provided insufficient protections for human research participants.[39]

In 1974, outrage over the Tuskegee Syphilis Study[40] led to the enactment of the National Research Act,[41] thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter "Commission").[42] In addition to proposing general ethical guidelines to ensure the protection of research subjects, the Commission was given the responsibility of identifying especially vulnerable groups, such as children, and providing recommendations for their protection.[43] The Belmont Report (hereinafter "Report") provides a summary of ethical guidelines identified during the Commission's deliberations, and is a statement aimed toward resolving the ethical problems of research with human participants in the United States.[44] A specific directive of the Commission included the consideration of "the nature and definition of informed consent in various research settings."[45]

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[38] Faden, Lederer & Moreno, *supra* note 27, at 1670 (discussing the scientific community's discomfort with the Nuremberg Code and the welcome variation in ethical principles established by the Declaration of Helsinki).

[39] *Id.* The author explains that although researchers became more aware of the need for ethical treatment of human subjects, the Nuremberg Code and the Declaration of Helsinki were ineffective in providing adequate protections against abuse of participants in human research. *Id.* The author states that this was shown through the occurrence of infamous events such as the thalidomide episode, the Willowbrook study, and the Tuskegee study. *Id. See* discussion *infra* Part I.B.

[40] Lehrman & Sharav, *supra* note 18, at 250; Richard Delgado & Helen Leskovac, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV 67, 71 (1986).

[41] National Research Act of 1974, Pub. L. No. 93-348 (1974); See JAMES JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (1981) for full account of the Tuskegee Syphilis Study. The study involved 399 black men in Macon County, Alabama who were in the late stage of syphilis at the beginning of the experiment. *Id.* The study did not involve any form of treatment, but was rather a nontherapeutic experiment designed to gather information on the progression of the disease. *Id.* Treatment was withheld, even after the discovery of penicillin as an effective treatment. *Id.* By the end of the study, at least 28 men, but possibly as many as 100, died from complications of syphilis and many others had developed serious conditions that contributed to their death. *Id.*

[42] BELMONT REPORT, *supra* note 2.

[43] Lehrman & Sharav, *supra* note 18, at 250.

[44] BELMONT REPORT, *supra* note 2, at Summary.

[45] *Id.*

The Report identifies three critical elements to informed consent: information, comprehension and voluntariness.[46] Informed consent of children is addressed with recognition of the need for special provisions for incompetent subjects whose comprehension may be significantly limited.[47] Obtaining consent from children when possible,[48] in addition to securing third party permission to protect children from harm, are identified as safeguards to ensure respect for such persons.[49] The Report's recommendations eventually led to the adoption of government regulations to protect human participants of scientific research,[50] including a section providing for special considerations in research with children.[51] The principles embodied in the Report remain the foundation of the federal guidelines currently in use.[52]

B. DEVELOPMENT OF FEDERAL REGULATIONS

In the years following World War II, widespread ethical violations in the United States indicated that the Nuremberg Code had failed to make a notable impact on the treatment of human participants in scientific research.[53] A significant episode contributing to the development of federal laws in human research was the thalidomide disaster in the United States, Canada and Europe.[54] Beginning in 1957, thousands of birth defects were shown to be caused by the investigational drug, thalidomide, which had been administered to innumerable pregnant women without proper informed consent.[55] Testimony at Senate hearings on the conduct of pharmaceutical companies revealed that drug companies had routinely supplied physicians with experimental drugs, which

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46 *Id.* at Part C, 1-3.

47 *Id.* at Part C.

48 *Id.* (recognizing that a participant's ability to understand may be limited by intelligence, maturity, language, and rationality and identifying children as a group in which comprehension may be severely limited).

49 *Id.* at Part C.

50 Lehrman &Sharav, *supra* note 18, at 250.

51 45 C.F.R. §§46.401-46.409 (1994); KOOCHER & KEITH-SPIEGEL, *supra* note 25, at 89.

52 *See* 45 C.F.R. § 46 (1994).

53 Faden, Lederer, & Moreno, *supra* note 27, at 1670.

54 ADVISORY COMMITTEE OF HUMAN RADIATION EXPERIMENTS REPORT, *at* http://tis.eh.doe.gov/ohre/roadmap/achre/overpt1.html (last visited Sept. 18, 2002).

55 *Id.*

had yet to be thoroughly tested to establish their safety for human consumption.[56] These drugs were then prescribed to patients, who consequently became subjects of a loosely controlled study without their informed consent.[57]

Largely as a result of the thalidomide tragedy, the Food, Drug, and Cosmetic Act of 1938 was amended in 1962 to require informed consent in the testing of investigational drugs.[58] The effect of the informed consent requirement was greatly minimized, however, by Congress' policy of restraint in becoming involved in the doctor-patient relationship.[59] In spite of the minimalized application of the amendments to the Food, Drug, and Cosmetic Act, they served to influence the future of governmental protections for human research participants.[60]

Additional studies provoking much publicity during the late 1960's and early 1970's further contributed to increased federal efforts to protect human participants.[61] One such study, the Willowbrook study, was carried out at Willowbrook State School for the Retarded in New York.[62] The study involved injecting mentally impaired children and adolescents with a mild form of hepatitis serum as part of a research study designed to contribute to the development of a prophylactic vaccine.[63] Prior to the study, a high number of the residents at the hospital were found to be infected with the hepatitis virus.[64] The study was justified by reasoning that the hospital's overcrowding and unsanitary conditions would result in most new patients eventually being infected, regardless of participation in the study.[65] Although informed consent from the parents was obtained, the content of the information provided to the parents was criticized as being deceptive and

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56 *Id.*

57 *Id.*

58 *Id.*; Food, Drug and Cosmetic Act amendments, 21 U.S.C. § 355 (1962).

59 ADVISORY COMMITTEE OF HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 54.

60 *Id.* (explaining that the amendments were influential in the advancement of research protections within the Department of Health, Education and Welfare, which would be the government body that eventually enacted 45 CFR § 46 as protections of human subjects in research).

61 *Id.*

62 *Id.*

63 *Id.*

64 *Id.*

65 *Id.*

coercive.[66] Commentators further criticized the study for attempting to infect children with the disease, rather than studying those children who became ill naturally.[67]

Another infamous study, the Tuskegee Syphilis Experiment, was designed to document the natural course of syphilis.[68] The participants in the study, 399 impoverished African American men in Alabama suffering from syphilis, were lured into the project with offers of free medical care.[69] The men were deceived with claims that they were being treated for "bad blood."[70] Treatment was deliberately withheld and great lengths were taken to prevent participants from obtaining treatment from any other source.[71] Despite the eventual discovery of penicillin as an effective treatment for syphilis, the study continued.[72] Because the participants believed they were receiving medical care, they did not seek treatment elsewhere.[73] Although the study was finally stopped in 1973, it left a legacy of at least 28 deaths and over 100 cases of blindness and insanity caused by the untreated syphilis.[74]

Public outcry over such abuses in scientific research led Congress to respond with the enactment of the National Research Act in 1974.[75] This Act established the National Commission for the Protection of Human subjects of Biomedical and Behavioral Research (hereinafter "Commission").[76] The National Research Act required the Department of Health, Education and Welfare (hereinafter "DHEW") to codify policies for the protection of human subjects in scientific research.[77]

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[66] *Id.* The consent form was criticized as appearing to state that the children would be receiving a vaccine against the virus. *Id.* In addition, coercion may have been indicated by offerings to parents of more rapid admission to the school if enrolled in the hepatitis study. *Id.*

[67] *Id.*

[68] See JONES, *supra* note 41, for full account of the Tuskegee Syphilis Study; The Tuskegee Syphilis study was conducted by the U.S. Public Health Service from 1932-1972. *Id.*

[69] *Id.*

[70] *Id.*

[71] *Id.*

[72] ADVISORY COMMITTEE OF HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 54.

[73] *Id.*

[74] *Id.*

[75] National Research Act of 1974, Pub. L. No. 93-348 (1974).

[76] BELMONT REPORT, *supra* note 2, at Summary.

[77] ADVISORY COMMITTEE OF HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 54.

The resulting federal regulations, first drafted in 1974, were then reviewed by the Commission, which then issued reports and recommendations for revisions of the proposed regulations.[78] The Commission's reports were the basis of the revisions to the federal guidelines, promulgated by the DHEW in 1979, which received final department approval in 1981.[79] In 1983, based on the Commission's recommendations, additional regulations were enacted in an attempt to address the unique issues involved in protecting the rights and welfare of children in research.[80]

C. CURRENT FEDERAL REGULATIONS

Current federal regulations and guidelines for the protection of human research subjects are set forth in the Code of Federal Regulations (hereinafter "Regulations").[81] The Regulations apply to all research involving human participants conducted, supported or otherwise subject to regulation by any federal department or agency.[82] Therefore, projects not federally funded or regulated are not legally mandated to comply with the protections provided by the Regulations.[83] Funding from any source, however, would likely be denied to those not demonstrating similar protections for human participants.[84] Furthermore, individual states may provide additional protections for human research participants beyond those covered by federal law.[85] To assure compliance with the federal ethical guidelines, all research covered by the Regulations must be reviewed and approved by an Institutional Review Board (hereinafter "IRB").[86] The IRB is required to

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[78] OFFICE OF HUMAN SUBJECTS RESEARCH: GUIDELINES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS AT THE NATIONAL INSTITUTE OF HEALTH, *available at* http://ohsr.od.nih.gov/guidelines.php3 (last modified March 2, 1995).

[79] 45 C.F.R. § 46 (1994); The Department of Health, Education and Welfare was renamed the Department of Health and Human Services.

[80] 45 C.F.R. §§46.401-46.409 (1994).

[81] 45 C.F.R. § 46 (1994).

[82] 45 C.F.R. §46.101 (1994).

[83] *Id.*

[84] KOOCHER & KEITH-SPIEGEL, *supra* note 25, at 90.

[85] 45 C.F.R. § 46.101(f) (1994) (stating "This policy does not affect any state or local laws or regulations, which may otherwise be applicable, and which provide additional protections for human subjects.").

[86] 45 C.F.R. § 46.103(b) (1994).

make timely reviews of the research project,[87] while maintaining authority to suspend or terminate its approval throughout the duration of the study.[88]

The Regulations provide extensive requirements for informed consent of a research participant, or alternatively, for the consent of the participant's legal representative.[89] With some variations, the general requirements of informed consent outlined by the Regulations parallel those found in earlier international and national codes of ethics.[90] Consent must be obtained under conditions that minimize any possible coercion or undue influence.[91] The information provided to participants must be in language that the participants or their legal representative can understand.[92] In addition, informed consent must not include exculpatory language that serves as a waiver of the participant's legal rights or provides the researcher or institution a release from liability for negligence.[93] Basic elements of informed consent identified by the Regulations include a description of the research and its procedures;[94] a description of reasonably foreseeable risks or discomforts;[95] a description of reasonably expected benefits to the participants or others;[96] disclosure of alternative procedures or treatment the participant may find effective;[97] a statement describing the extent of confidentiality;[98] information and an explanation regarding compensation and medical treatment for possible injuries;[99] the identity of a contact person for answers to any

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87 45 C.F.R. § 46.109 (1994).

88 45 C.F.R. § 46.113 (1994).

89 45 C.F.R. § 46.116 (1994) (stating "Except 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.").

90 Jay Katz, *The Nuremberg Code and the Nuremberg Trial: A Reappraisal*, 276, JAMA, 1662, 1665 (1996) (arguing that requirements of informed consent in Federal Regulations do not compare to the stringent requirements found in the Nuremberg Code); *see also* 45 C.F.R. § 46 (1994); Nuremberg Code, *supra* note 1; DECLARATION OF HELSINKI, *supra* note 2; BELMONT REPORT, *supra* note 2.

91 45 C.F.R. § 46.116 (1994).

92 *Id.*

93 *Id.*

94 45 C.F.R. §.46.116(a)(1) (1994).

95 45 C.F.R. §.46.116(a)(2) (1994).

96 45 C.F.R. § 46.116(a)(3) (1994).

97 45 C.F.R. § 46.116(a)(4) (1994).

98 45 C.F.R. § 46.116(a)(5) (1994).

99 45 C.F.R. § 46.116(a)(6) (1994).

questions regarding the research;[100] and an assurance that participation is voluntary and may be discontinued at any time without penalty or loss of benefits.[101]

The Regulations provide additional protections for research with children.[102] The section defines children as "persons, who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."[103] In most jurisdictions, persons under the age of 18 will not have attained the necessary legal age to consent to scientific research.[104] The Regulations also define new terminology to provide clarity to the term "informed consent," as it is used in research with children.[105] "Consent" is a legal term that implies full competence to make an independent decision for oneself and that "cannot be appropriately delegated to others."[106] Since children are not legally competent to give informed consent on their own behalf, a child's "consent" is not generally sufficient.[107] Therefore, a child must give his or her "assent," meaning an affirmative agreement to partake in the research,[108] while a parent or guardian must give "permission" for the child to participate.[109] Guidelines for protection of children are classified according to the risk and potential

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100 45 C.F.R. § 46.116(a)(7) (1994).

101 45 C.F.R. § 46.116(a)(8) (1994).

102 45 C.F.R. § 46, Subpart D (1994).

103 45 C.F.R. § 46.402(a) (1994).

104 King & Churchill, *supra* note 9, at 719.

105 Katerberg, *supra* note 4, at 551 (stating that Subpart D of the Federal Regulations adopts new terminology in order to avoid the confusion associated with the term "informed consent" as it applies to children).

106 KOOCHER & KEITH-SPIEGEL, *supra* note 25, at 105.

107 Katerberg, *supra* note 4, at 551.

108 45 C.F.R. § 46.402(b) (1994).

109 45 C.F.R. § 46.402(c) (1994); *see also* NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN 12-13 (1977) [hereinafter NATIONAL COMMISSION]. The Report states:

The Commission uses the term parental or guardian "permission," rather than "consent," in order to distinguish what a person may do autonomously (consent) from what one may do on behalf of another (grant permission). Parental permission normally will be required for the participation of children in research. In addition, assent of the children should be required when they are seven years of age or older. The Commission uses the term "assent" rather than "consent" in this context, to distinguish a child's agreement from a legally valid consent.

Id. at 13.

benefit involved in the research.[110] Generally, as the risk to the child participant increases and the benefit to the child becomes more remote, the restrictions on the research grow more stringent.[111] The classification of the research involved, however, does not affect the requirement of obtaining the assent of the child or the permission of the parent or guardian.[112] Nor does the classification have an impact on the determination of when such assent or permission can be waived.[113]

The child's assent must be solicited when the IRB, taking into account the child's age, maturity, and psychological state, determines that the child is capable of providing assent.[114]

Rather than requiring researchers to obtain assent from a child starting at a specific age, determination of the assent requirement is made on an individual case basis.[115] To ensure respect for children, obtaining assent is particularly obligatory when the research: "(1) does not involve interventions likely to be of benefit to the subjects; and (2) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others."[116] On the other hand, the Regulations provide for an exception to the requirement of child assent.[117]

> If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the

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110 45 C.F.R. §§ 46.404-407 (1994).

111 Katerberg, *supra* note 4, at 550 (stating that the categories in the Regulations establish a sliding scale, which determines the standard of review required by the IRB).

112 45 C.F.R. §§ 46.404, 46.405(c), 46.406(d), 46.407(b)(2)(iii) (1994) (all sections stating that the IRB must find that "adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408"); *see also* 45 C.F.R. § 46.408 (1994).

113 45 C.F.R. §§ 46.404, 46.405(c), 46.406(d), 46.407(b)(2)(iii) (1994) (all sections stating that the IRB must find that "adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408"); *see also* 45 C.F.R. § 46.408 (1994).

114 45 C.F.R. § 46.408(a) (1994).

115 *Id.*

116 OFFICE FOR HUMAN RESEARCH PROTECTIONS: IRB GUIDEBOOK, VI(C) (last modified June 21, 2001), *at* http://ohrp.osophs.dhhs.gov/irb/irb_chapter6.htm.

117 45 C.F.R. § 46.408(a) (1994).

children is not a necessary condition for proceeding with the research.[118]

Therefore, even for those children capable of providing assent, such assent is not required when research offers a direct therapeutic benefit to the child and is only available in the context of research.[119]

Parental permission must always be obtained in the cases of research with children, absent any applicable exceptions.[120] Depending on the risks and benefits of the research, the researcher may be required to obtain the permission of one or both parents.[121] The Regulations allow for only one parent's consent in research that involves minimal risk.[122] If the research involves greater than minimal risk, but presents the prospect of direct benefits to the child, one parent's consent may also be sufficient.[123] Consent of both parents is required in research involving greater than minimal risk and no prospect of a direct benefit to the child, but likely to yield generalizable knowledge about the child's condition.[124] Both parents must also consent to research, not otherwise approvable under the Regulations, that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.[125] Consent may be further complicated

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[118] *Id.*

[119] *See id.*

[120] 45 C.F.R. § 46.408(b)-(c) (1994); 45 C.F.R. § 46.408(c) (1994) (provides for exceptions to parental permission). See *infra* Part II for discussion of additional statutory and common law doctrines that allow for exceptions to parental permission.

[121] 45 C.F.R. § 46.408(b) (1994).

[122] 45 C.F.R. §§ 46.404 (1994); 45 C.F.R. § 46.408(b) (1994) ("Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 46.404 or § 46.405.").

[123] 45 C.F.R. §§ 46.405 (1994); 45 C.F.R. § 46.408(b) (1994) ("Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 46.404 or § 46.405").

[124] 45 C.F.R. §§ 46.406 (1994); 45 C.F.R. § 46.408(b) (1994) ("Where research is covered by §46.406 and §46.407, and permission is to be obtained from parents, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.").

[125] 45 C.F.R. §§ 46.407 (1994); 45 C.F.R. § 46.408(b) (1994) ("Where research is covered by §46.406 and §46.407, and permission is to be obtained from parents, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.").

when the child's parents are separated or divorced.[126] Depending on the jurisdiction, conducting research with a child without the consent of the custodial parent may give rise to civil liability or professional disciplinary action.[127] There are, however, statutory and common law exceptions to the requirement of parental permission, as well as limits to the extent of parental authority to provide consent on behalf of children to participate in nontherapeutic research.

II. EXTENT OF PARENTAL PERMISSION FOR RESEARCH WITH CHILDREN

A. WHEN IS PARENTAL PERMISSION NOT NECESSARY?

1. Federal Regulations[128]

The requirement of parental permission may be waived if the IRB determines that permission is not a reasonable requirement to protect the participants, and when the appropriate mechanisms are provided for protecting the child's

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[126] Mark B. DeKraai & Bruce D. Sales, *Liability in Child Therapy and Research*, 59, J. CONSULTING CLINICAL PSYCHOL., 853, 855 (1991).

[127] *Id.* The authors cite Dymek v. Nyquist, 469 N.E.2d 659 (1984), in which the custodial parent filed an action against a psychiatrist for unauthorized treatment of the child. *Id.* In reversing the lower court's dismissal of the complaint, the appellate court held that the psychiatrist "had no authority to subject a child to psychotherapy...without lawful consent of either...[the] custodial parent, or the court...In essence, [the psychiatrist's] actions over the one-year period of psychotherapy constituted a most severe interference with plaintiff's custodial prerogatives and duties in the area of his minor child's health care...." *Id.* The authors also cite White v. North Carolina State Board of Examiners of Practicing Psychologists, 388 S.E.2d 148 (1990), a case involving disciplinary action against a psychotherapist who conducted therapy with a minor without the custodial parent's knowledge or consent. *Id.* The court affirmed the ruling of the licensing board, that the psychotherapist violated the ethical principle: "In their professional roles, psychologists avoid any action that will violate or diminish the legal and civil rights of clients or of others who may be affected by their actions." *Id.* The authors also acknowledge that not all states require the consent of a custodial parent for treatment or research, but that it would be prudent to obtain both parents' consent unless the law is clear in that such action is unnecessary. *Id.*

[128] The exception discussed in this section regarding the federal regulations only refers to the exception to parental permission that applies specifically to research with children. Research may be exempted entirely from the federal regulations (45 C.F.R. § 46.101(b) (1994)). The requirement of informed consent for both adults and children may also be waived under certain conditions for minimal risk research (45 C.F.R. §46.116(d) (1994)); See Katerberg, *supra* note 4, for a full discussion of exemptions under the framework of the federal regulations.

interests.[129] In particular, a waiver may be obtained in research on neglected or abused children,[130] where the interests of the parent and the child may conflict.[131] Successful child maltreatment research may allow for the delineation of risk factors that predispose children to abuse and neglect, that may then lead to the development of early interventions or effective treatment.[132] Child-abuse reporting statutes may impose a duty on researchers to report incidents of child abuse or neglect revealed in the course of research.[133] Reports of child abuse may then result in legal, social or work-related repercussions for the parents of the abused child.[134] Such possible consequences of allowing their child to participate in the research may deter parents from granting their permission.[135] A requirement of parental consent would therefore prevent researchers from conducting studies that may lead to future benefits and services for neglected and abused children.[136] In the case of child maltreatment research, given the possible benefits of the research to children and the inherent risk to parents, parents may not be in a position to decide what is best for their child.[137] Accordingly, the Regulations specifically identify "neglected or abused children" as a population for whom parental consent may be waived.[138] As "neglected or abused children" is the only example provided by the Regulations for the purposes of the discussed exception, whether other situations or groups of children may apply remains unclear and has been a topic of academic debate.[139]

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129 45 C.F.R. § 46.408(c) (1994).

130 *Id.*

131 King & Churchill, *supra* note 9, at 720.

132 Jonathan B. Kotch, *Ethical Issues in Longitudinal Child Maltreatment Research*, 15, J. INTERPERSONAL VIOLENCE, 696, 703 (2000).

133 DeKraai & Sales, *supra* note 126, at 857-858; Kotch, *supra* note 132, 699.

134 Kotch, *supra* note 132, at 698-704.

135 *Id.*

136 *See id.*.

137 King & Churchill, *supra* note 9, at 720.

138 45 C.F.R. § 46.408(c) (1994) (stating that parent permission can be waived if such permission is not a reasonable requirement to protect the subjects and providing the specific example of neglected or abused children).

139 Katerberg, *supra* note 4, at 564 (exploring views of different commentators in a discussion regarding whether 45 C.F.R. § 46.408(c) (1994) is meant to include only "neglected or abused children" or is used as just one of many possible examples).

2. Emancipated Minors

Emancipation is the act by which, "a child may be released from some or all of the disabilities of childhood and receive the rights and duties of adulthood even before reaching the age of majority."[140] The emancipated minor doctrine recognizes minors as legal adults if they have achieved a certain amount of independence from their parents even though they have not yet reached the age of majority.[141] Several states have enacted statutes that outline the conditions under which minors may become emancipated[142] and provide for the legal rights accompanying emancipation.[143] Minors may become emancipated through judicial decree, marriage, parental consent, parental failure of legal responsibilities or demonstration of separate living and self support.[144] In addition, some states regard minors as emancipated if they are on active duty with the United States Armed Forces.[145] Absent statutory provisions for emancipation, state courts may rely on common law in considering the emancipation petition of a minor.[146] Significant to scientific research, an emancipated minor is considered an adult for the purpose of providing legally effective informed consent to any health-related treatments and procedures.[147] Emancipation statutes do not

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[140] ALAN SUSSMAN & MARTIN GUGGENHEIM, THE RIGHTS OF PARENTS 58 (1980).

[141] DeKraai & Sales, *supra* note 126, at 853; King & Churchill, *supra* note 9, at 720.

[142] *E.g.*, CAL. FAM. CODE § 7002 (West 2002), WYO. STAT. ANN. § 14-1-101 (Michie 2002), COLO. REV. STAT. ANN. § 13-22-103 (West 2002), N.M. STAT. ANN. § 32A-21-3 (Michie 2002), N.Y. PUB. HEALTH § 2504 (McKinney 2002).

[143] *E.g.*, CAL. FAM. CODE § 6922 (West 2002), CAL. FAM. CODE § 7050 (West 2002), N.Y. PUB. HEALTH §2504 (McKinney 2002), N.M. STAT. ANN §24-10-1 (Michie 2002), COLO. REV. STAT. § 13-22-103 (West 2002), MICH. COMP. LAWS ANN § 722.4e (West 2002).

[144] George J. Annas, Leonard H. Glantz, & Barbara F. Katz, *Law of Informed Consent in Human Experimentation: Children*, 2-13 (in NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, APPENDIX TO REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN (1977)); *see also e.g.*, CAL. FAM. CODE § 7002 (West 2002); WYO. STAT. ANN § 14-1-101 (Michie 2002); COLO. REV. STAT. § 13-22-103 (West 2002); N.M. STAT. ANN § 32A-21-3 (Michie 2002); N.Y. PUB. HEALTH §2504 (McKinney 2002).

[145] *E.g.*, CAL. FAM. CODE § 7002(b) (West 2002), N.M. STAT. ANN § 32A-21-3(B) (Michie 2002).

[146] *See e.g.*, In the Matter of S.L., a Minor Child v. A. and Sh.L. 735 A.2d 433 (recognizing case law as supporting authority for emancipation, although no specific state statute provided a definition or procedure for emancipation).

[147] *E.g.*, CAL. FAM. CODE § 7050(e)(1) (West 2002); N.Y. PUB. HEALTH § 2504(1) (McKinney 2002); N.M. STAT. ANN § 24-10-1 (Michie 2002); MICH. COMP. LAWS ANN. §

specifically mention consent to scientific research, and the issue has not been addressed by the courts.[148] Thus, whether statutes authorizing minors to consent to medical treatment extend to scientific research is controversial.[149]

3. Mature Minor Doctrine

"A minor may consent to participate in treatment or research when he or she is close to the age of majority, is able to comprehend the nature and impact of participation, and knowingly gives informed consent."[150] The mature minor rule provides that anyone who has sufficient maturity and intelligence to give informed consent to undergo a procedure can do so without the consent of a parent or guardian.[151] Several states have adopted a statutory or common law mature minor exception to the requirement of parental consent in the treatment of a minor.[152] In *Cardwell v. Bechtol*, the Supreme Court of Tennessee established the mature minor exception in holding that a 17-year-old senior in high school, "a mature young woman who acted somewhat older than her age,"[153] was

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722.4E(1)(g) (West 2002).

148 *See* Katerberg, *supra* note 4, at 561-564.

149 DeKraai & Sales, *supra* note 126, at 854 (interpreting the legal right to consent to treatment to also include research); Katerberg, *supra* note 4, at 558-563. Children is defined by 45 C.F.R. § 46.402(a) as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." *Id.* at 558. Katerberg argues that since emancipated minors can consent to any treatment or procedure, this may imply that 45 C.F.R. § 46 Subpart D does not apply to research involving emancipated minors and therefore consent of the minor is sufficient. *Id.* at 558-560. Katerberg also points out dicta in a federal court which stated that a Louisiana statute that gave minors the authority to provide effective legal consent would presumably extend to research. *Id.* at 559. The opposing viewpoint of Robert Veatch is discussed, who argues that "statutes [authorizing mature minors to consent to medical or surgical care] cannot, however, be taken to authorize adolescent consent for research procedures." *Id* at 561; King & Churchill, *supra* note 9, at 720 (stating, "Emancipated minors are legal adults, for most or all purposes, and therefore might also qualify as adults for the purposes of consent to research participation); KOOCHER & KEITH-SPIEGEL, *supra* note 25, at 108 (explaining that state laws do not preempt federal policy and therefore a state law authorizing a minor to consent to certain treatments does not necessarily imply that the authorization extends to the research component of that treatment).

150 DeKraai & Sales, *supra* note 126, at 854.

151 Annas, Glantz, & Katz, *supra* note 144, at 2-16.

152 *E.g.*, NEV. REV. STAT. 129.030(2) (1983); N.H. REV. STAT. ANN. § 318-B:12-a (1984).

153 Cardwell v. Bechtol, 724 S.W.2d 739, 743 (1987).

legally competent to consent to medical treatment.[154] The court stated:

> Whether a minor has the capacity to consent to medical treatment depends upon the age, ability, experience, education, training, and degree of maturity or judgment obtained by the minor, as well as upon the conduct and demeanor of the minor at the time of the incident involved. Moreover, the totality of the circumstances, the nature of the treatment and its risks or probable consequences, and the minor's ability to appreciate the risks and consequences are to be considered.[155]

The Supreme Court of West Virginia followed Tennessee in recognizing its own common law mature minor exception.[156] Similarly, in Kansas, a 17-year-old minor was found mature enough to understand the nature and consequences of a procedure to treat his damaged finger and therefore could give effective informed consent.[157] Mature minors have also secured the right to refuse life-sustaining medical treatment.[158] Similar to the emancipated minor doctrine, there is disagreement as to whether the legal capacity given to mature

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[154] *Id.* at 749.

[155] *Id.* at 748.

[156] Belcher v. Charleston Area Medical Center, 422 S.E.2d 827. After outlining the analysis of the Tennessee court in Cardwell, the court stated: "We agree with the holding of Cardwell, and we believe that the mature minor exception is part of the common law rule of parental consent of this state." *Id.* at 837.

[157] Younts v. St. Francis Hospital and School of Nursing, Inc., 469 P.2d 330.

[158] In re E.G., a Minor, 549 N.E.2d 322 (1990). The minor refused to consent to blood transfusions, claiming that it would violate her personal religious convictions rooted in the Jehovah's Witness faith. *Id.* The court held that a sufficiently mature minor has the limited right to consent to or refuse life-sustaining medical treatment. *Id.* at 327-328. However, [t]he right must be balanced against four State interests: (1) the preservation of life; (2) protecting the interests of third parties; (3) prevention of suicide; and (4) maintaining the ethical integrity of the medical profession." *Id.* at 328. The court also noted that protecting the interests of third parties was most significant in this case and would be applicable to the parents. *Id.* If the parents had opposed the minor's refusal of treatment, rather than approve as in this case, the opposition would be a heavy consideration against the minor's right to refuse. *Id.* See Novak v. Cobb County-Kennestone Hospital Authority 849 F.Supp. 1559 for opposing view in Georgia. A sixteen-year-old Jehovah's Witness brought action against those involved in court-ordered blood transfusions, which were refused by the minor due to religious beliefs. *Id.* The United States District Court concluded that Georgia does not recognize the right of a mature minor to refuse medical treatment and that such a right was not guaranteed by the First or Fourteenth Amendments of the Constitution. *Id.* at 1574-1576.

minors to consent to their own treatment extends to scientific research.[159]

4. Exceptions for Certain Services or Conditions

Minors may consent to treatment for certain medical conditions without the knowledge or permission of their parents.[160] Several states provide an exception to the requirement of parental permission and allow minors to give effective legal consent for specific services or conditions.[161] Such legislation was enacted in response to children who would not involve their parents in their treatment for certain conditions and would therefore be denied access to valuable services if parental permission was required.[162] Types of services or conditions covered vary according to specific state legislation, but may include services related to pregnancy,[163] sexual assault,[164] drug and alcohol abuse,[165] venereal disease[166] and mental health treatment.[167] It follows that the assent of minors should be sufficient for scientific research involving those same conditions for which minors can legally consent on their own behalf.[168] If parental permission were required for

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159 *See supra* note 149 and accompanying text.

160 NATIONAL COMMISSION, *supra* note 109, at 18.

161 *Id.*

162 Katerberg, *supra* note 4, at 560 (citing Leonard H. Glantz, *The Law of Human Experimentation with Children*, in CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW 112 (Michael A. Grodein & Leondard H. Glantz eds., 1994)).

163 *E.g.*, CAL. FAM. CODE § 6925(a) (West 2002); MISS. CODE ANN. § 41-41-3(3) (2002); N.C. GEN. STAT. § 90-21.5(a)(ii) (2002); see Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52 (1976) and Carey v. Population Services International 52 L. Ed. 2d . 675 (1977) for cases providing this right.

164 *E.g.*, CAL. FAM. CODE § 6927-6928 (West 2002).

165 *E.g.*, CAL. FAM. CODE §6929(b) (West 2002); N.C. GEN. STAT. § 90-21.5(a)(iii) (2002).

166 *E.g.*, CAL. FAM. CODE § 6926 (West 2002); N.C. GEN. STAT. § 90-21.5(a)(i) (2002); N.Y. PUB. HEALTH §2305(2) (McKinney 2002).

167 *E.g.*, CAL. FAM. CODE § 6924(b) (West 2002); N.C. GEN. STAT. § 90-21.5(a)(iv) (2002).

168 Katerberg, *supra* note 4, at 558-562 (suggesting that state legislation allowing minors to give effective consent to certain services suggests that 45 C.F.R. § 46, Subpart D, which defines "children" as those who have not attained the legal age for consent to treatments or procedures involved in the research, does not apply to research involving treatment of conditions identified by such legislation since the definition of "children" equates the age for research consent with the age for treatment consent); *see also* NATIONAL COMMISSION, *supra* note 109, at 18. The Report explains that the absence of the requirement of parental permission for certain types of

participation in research in such cases, it would most likely prevent the development of improved preventative interventions and treatments.[169]

B. HAVE THE COURTS LIMITED PARENTAL AUTHORITY?

A recent case addressed the issues of informed consent and the extent of parental authority in allowing children to participate in nontherapeutic research.[170] *Grimes v. Kennedy Krieger Institute, Inc.*[171] involved two negligence actions against Kennedy Krieger Institute, Inc. (hereinafter "KKI") in which the plaintiffs alleged that their children were poisoned, or exposed to the risk of being poisoned, by the accumulation of lead dust in their blood while participating in a research study with KKI.[172] KKI, a prestigious research institute associated with Johns Hopkins University, created a nontherapeutic research program to determine the effectiveness of varying

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treatment provided to minors infers that research regarding such treatment could also be conducted without parental permission. *Id.* The Report states:
A number of states have specific legislation permitting minors to consent to treatment for certain conditions (e.g., pregnancy, drug addiction, venereal diseases) without the permission (or knowledge) of their parents. If parental permission were required for research about such conditions, it would be difficult to develop improved methods of prevention and therapy that meet the special needs of adolescents. Therefore, assent of such mature minors should be considered sufficient with respect to research about conditions for which they have legal authority to consent on their own to treatment.
Id.

169 NATIONAL COMMISSION, *supra* note 109, at 18.

170 Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 807 (Md. 2001). As defined by the court, "Nontherapeutic 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 (or, under some circumstances, for profit)." *Id.* at 812. The court also referred to the description of non-therapeutic experimental research by Karine Morin, "any manipulation, observation, or other study of a human being – or of anything related to that human being that might subsequently result in manipulation of that human being – done with the intent of developing new knowledge and which differs in any form from customary medical (or other professional) practice." *Id.* at 836. See Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 165-168 (1998) for full discussion on distinguishing between treatment and experimentation.

171 Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 807 (Md. 2001). The Circuit Court for Baltimore City granted KKI's motion for summary judgment and the plaintiffs appeal. *Id.* In the present case, the Court of Appeals of Maryland vacated the rulings of the Circuit Court and remanded the cases for further proceedings consistent with the Court's opinion. *Id.* The case is still awaiting trial. *Id.*

172 *Id.* at 818.

levels of lead paint abatement procedures.[173] The ultimate goal of the study was to find economical partial lead abatement procedures to prevent landlords of low income urban housing from abandoning the properties due to the great expense of completely eliminating lead from the homes.[174] The project required that young children be living in the housing during the entire course of the study.[175] Children were necessary participants in the study since they are particularly sensitive to the accumulation of lead in the body.[176] KKI encouraged the landlords of the homes to rent the premises to families with small children to ensure the participation of children in the study.[177] Effectiveness of the abatement procedures was determined by measuring the levels of lead dust remaining in the homes after the lead abatement procedures were completed.[178] Lead levels were measured by comparing the lead contamination found in the children's blood to levels of lead dust found in the houses over a two-year period.[179] The researchers anticipated that the children may accumulate lead in their blood from the dust, thus helping to determine the effectiveness of the various partial abatement methods.[180] The plaintiffs alleged that KKI was negligent in failing to give immediate warning of the hazardous levels of lead that KKI discovered in the homes during the course of the study.[181] Further, in one case, KKI gave notice of the toxic levels in the home only after elevated levels of lead in the children's blood was revealed in blood tests.[182] Although the role of the court of

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173 *Id.* at 812.

174 *Id.* at 821.

175 *Id.*

176 *Id.* at 812 (Md. 2001). The court quoted an article reporting on an earlier study performed by the same researchers of the current research project, Mark R. Farfel & J. Julian Chisolm, *Health and Environmental Outcomes of Traditional and Modified Practices for Abatement of Residential Lead-Based Paint*, 80 AM. J. PUB. HEALTH, 1240, 1243 (1990), "[e]xposure to lead-bearing dust is particularly hazardous for children because hand-to-mouth activity is recognized as a major route of entry of lead into the body and because absorption of lead is inversely related to particular size." *Id.*

177 *Id.* KKI encouraged landlords to participate in the study and recruit families with young children by helping the landlords obtain grants or loans for the lead abatement procedures. *Id.*

178 *Id.* at 812.

179 *Id.*

180 *Id.* at 812-813.

181 *Id.* at 825-826. See *id.* at 825-832 for a full sequence of events and detailed description of the tests conducted and their findings.

182 *Id.* at 825-826.

appeals was only to determine whether the trial court erred in granting summary judgment to KKI, the court's ruling carried a great deal of legal significance in the area of nontherapeutic research on children.[183]

In its analysis of the effectiveness of parental consent, the court in *Grimes* looked for guidance from the only other court addressing the issue of nontherapeutic research with incompetent participants.[184] In *T.D. v. New York Office of Mental Health*, plaintiffs brought suit challenging regulations of the New York Office of Mental Health.[185] The challenged regulations governed nontherapeutic research on mental patients, some of whom were minors.[186] The provisions for substitute consent by surrogate decision makers, which included parental consent for child participants, became a central issue in the court's analysis.[187] Provisions in the regulations, authorizing parents to consent on behalf of children for participation in greater than minimal risk non-therapeutic research, were held to be unacceptable.[188] In justifying its holding, the court distinguished between a parent's right to consent to a child's medical treatment and a

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[183] Leonard H. Glantz, *Nontherapeutic Research with Children: Grimes v. Kennedy Krieger Institute*, 92 AM. J. PUB. HEALTH 1070, 1071 (2002); Grimes v. Kennedy Krieger Institute, Inc. 782 A.2d 807 (Md. 2001). The holding of the court included:
[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 health of the subject.... [I]nformed consent agreements in nontherapeutic research projects, under certain circumstances can constitute contracts; and that, under certain circumstances, such research agreements can, as a matter of law, constitute "special relationships" giving rise to duties, out of the breach of which negligence action may arise....[N]ormally, such special relationships are created between researchers and the human subjects used by the researchers.... [G]overnmental regulations can create duties on the part of researchers toward human subjects out of which "special relationships" can arise....fact issues as to existence of duty precluded summary judgment.
Id. at 858.

[184] T.D. v. New York Office of Mental Health, 650 N.Y.S.2d 173; Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 807, 811 (Md. 2001) (stating that the issues presented in the case involving consent in research have only been addressed by one other court, T.D. v. New York State Office of Mental Health); Glantz, *supra* note 183, at 1073 (stating that Grimes and T.D. are the only two courts addressing the issue of nontherapeutic research with nonconsenting subjects).

[185] T.D. v. New York Office of Mental Health, 650 N.Y.S.2d 173.

[186] *Id.* at 175

[187] *Id.* at 185.

[188] *Id.* at 191.

parent's right to volunteer a child for research that proposes no potential benefit to the child, stating:

> We are not dealing here with parental choice among reasonable treatment alternatives, but with a decision to subject the child to nontherapeutic treatments and procedures that may cause harmful permanent or fatal side effects. It follows therefore that a parent or guardian, let alone another adult who may be a member of the child's family, 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....[189]

The *Grimes* court concurred with the assessment in *T.D. v. New York Office of Mental Health*[190] and consequently held that a parent, or other applicable surrogate, in the state of Maryland, could not consent to a child's participation in nontherapeutic research that posed any risk of injury to the child.[191] In the court's view, "consent of a parent alone cannot make appropriate that which is innately inappropriate."[192] In support of its holding, the court reasoned:

> Whatever the interests of a parent, and whatever the interests of the general public in fostering research that might, according to a researcher's hypothesis, be for the good of all children, this Court's concern for the particular child and particular case, over-arches all other interests. It is, simply, and we hope, succinctly put, not in the best interest of any healthy child to be intentionally put in a nontherapeutic

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189 *Id.*, at 192.

190 Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 807, 856 (Md. 2001).

191 *Id.* at 858; *see* Anna C. Matroianni & Jeffrey P. Kahn, *Risk and Responsibility: Ethics, Grimes v. Kennedy Krieger, and Public Health Research Involving Children*, 92 AM. J. PUB. HEALTH 1073, 1073 (2002) (stating that the "court had challenged the acceptable level of risk in pediatric research studies, concluding that parents in the state of Maryland could not consent to their minor children's participation in research that posed even a minimal risk of harm if it offered no prospect of direct medical benefit to the subjects"). The court's initial holding appeared to conflict with 45 C.F.R. § 46 by making parental permission ineffective as consent when the research posed any risk to the child, as compared to the minor increase over minimal risk allowed in the federal regulations. *See* 45 C.F.R. § 46.406 (1994) (allowing for permission of parents in research involving greater than minimal risk and no prospect of direct benefit to the child when the risk is a minor increase over minimal risk).

192 Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 807, 855 (Md. 2001).

> situation where his or her health may be impaired, in order to test methods that may ultimately benefit all children.[193]

The holding in *Grimes* "sent shockwaves through the public health research community," as the court appeared to challenge the level of risk allowed in pediatric research by the federal regulations.[194] The scientific community feared that the court's holding meant the end for many current studies involving children and foreshadowed judicial intervention in future research projects.[195] In response to the possible implications of the decision, several amici curiae submitted briefs on a motion for reconsideration, centering on the issue of the extent of parental authority in providing informed consent on behalf of children.[196] Although the motion for reconsideration was denied, the court clarified its position regarding the allowable risk in nontherapeutic research with children.[197] The court explained that by "any risk," it meant "any articulable risk beyond the minimal kind of risk that is inherent in any endeavor."[198] The court further explained that, "[t]he context of the statement was a nontherapeutic study that promises no medical benefit to the child whatsoever, so that any balance between risk and benefit is necessarily negative."[199] It may be difficult to reconcile the first sentence of the court's explanation, which appears to allow for some level of risk, with the second sentence, which seems to imply that no risk is ever justified in nontherapeutic research when there is no prospect of a direct benefit to the child.[200] While the court attempted to align its holding with the standards set in the federal regulations, the standard for determining "minimal risk" in research with children remains unclear.[201] What

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193 *Id.*, at 853.

194 Matroianni & Kahn, *supra* note 191, at 1073.

195 *Id.*; Glantz, *supra* note 183, at 1071-1072.

196 Grimes v. Kennedy Krieger Institute, Inc. 782 A.2d 807, 861-862 (Md. 2001).

197 *Id.*

198 *Id.* at 862.

199 *Id.*

200 Glantz, *supra* note 183, at 1072.

201 *Id.*; Loretta M. Kopelman, *Pediatric Research Regulations Under Legal Scrutiny: Grimes Narrows their Interpretation*, 30 J.L. Med. & Ethics 38, 42 (2002) (discussing the two standards used to define minimal risk, the relativistic interpretation and the absolute interpretation). Minimal risk is defined under 45 C.F.R. § 46.102(i) as "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

should be clear from the only two cases addressing nontherapeutic research with children, is that obtaining parental consent does not immunize research from judicial intervention[202] and the scientific community would greatly benefit from a close analysis of the ethical issues addressed by the court.[203]

III. THE ROLE OF PARENTS AS SUBSTITUTE DECISIONMAKERS

Whether children should ever be allowed to serve as research participants is a matter of great debate.[204] Under the current law, however, children may participate in scientific research provided certain conditions are met and parental permission is obtained.[205] Parental proxy consent is rooted in the traditional view of children as mere chattel,[206] incompetent to make their own legal decisions.[207] The United States Supreme Court has repeatedly protected the rights of parents to control the conduct of children and make decisions on their behalf.[208] The Court has justified its deference to broad parental autonomy by pointing to "pages of human experience that teach that parents generally do act in the child's best interests."[209] The view of child-rearing as being within the

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the performance of routine physical and psychological examinations or tests." *Id.* Under the relativistic interpretation, minimal risk would be determined by the specific group being studied. *Id.* In contrast, the absolute interpretation uses the risks involved in the daily life of all children in general. *Id.*; *see also* Ross, *supra* note 4, at 162-163 (discussing the various interpretations of "minimal risk" in the federal regulations).

202 Matroianni & Kahn, *supra* note 191, at 1076.

203 Glantz, *supra* note 183, at 1073.

204 Ross, *supra* note 4, at 159-160 (discussing the academic debate regarding children serving as research subjects).

205 45 C.F.R. § 46 (1994), Subpart D; *see* discussion *infra* Part I.C.

206 AM. SOC'Y OF HUMAN GENETICS, *supra* note 9, at 1237 (citing G.B. Melton, *Children's Competence to Consent: A Problem in Law and Social Science*, in CHILDREN'S COMPETENCE TO CONSENT 113 (G.G. Melton & M.J. Saks eds., 1983)); NATIONAL COMMISSION, *supra* note 109, at 73.

207 Gerald P. Koocher & David R. Demaso, *Children's Competence to Consent to Medical Procedures*, 17 PEDIATRICIAN 68, 68 (1990) (stating that "children are presumed incompetent under the law in virtually all contexts"); Koocher, *supra* note 9. See Parham v. J.R., 442 U.S. 584 (1979), Ginsberg v. New York, 390 U.S. 629 (1968), Belotti v. Baird, 443 U.S. 622 (1979), and Thompson v. Oklahoma 487 U.S. 815 (1988) for cases recognizing the legal incompetence of children.

208 Parham v. J.R., 442 U.S. 584; Ginsberg v. New York, 390 U.S. 629; Belotti v. Baird, 443 U.S. 622.

209 Parham v. J.R., 442 U.S. 584, 602-603 (1979).

private sphere of the family unit and therefore deserving of protection from government interference is a fundamental value of Western society.[210] The principal justification underlying parental authority, and therefore the rights of parents to volunteer their children for nontherapeutic research, is the assumption that parents are in the best position and have the greatest interest in promoting the well-being of their children.[211] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has recognized, however, that there are occasions when parents may not act in the best interests of their children.[212] Identifying situations in which parental permission fails as a protective mechanism would allow for the establishment of effective alternative safeguards to protect children from harm.[213]

A. WHEN THE INTERESTS OF PARENT AND CHILD MAY CONFLICT

The best interests of parents and children are often contradictory, as the values, needs and desires of parents may be incongruent with those of their children.[214] Conflicts of

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[210] *See* Ginsberg v. New York, 390 U.S. 629, 638 (1968) (stating, "constitutional interpretation has consistently recognized that the parents' claim to authority in their own household to direct the rearing of their children is basic in the structure of our society."); Parham v. J.R., 442 U.S. 584, 602 (1979) (stating, "Our jurisprudence historically has reflected Western civilization concepts of the family as a unit with broad parental authority over minor children.); JAMES M. MORRISEY, ADELE D. HOFMANN & JEFFREY C. THROPE, CONSENT AND CONFIDENTIALITY IN THE HEALTH CARE OF CHILDREN AND ADOLESCENTS 4 (1986); Margaret O. Steinfels, *Children's Rights, Parental Rights, Family Privacy, and Family Autonomy, in* WHO SPEAKS FOR THE CHILD: THE PROBLEMS OF PROXY CONSENT 246-249 (Willard Gaylin & Ruth Macklin eds., 1982). Steinfels states that the protection of family from state interference has greatly depended on the constitutional protection of privacy. *Id.* at 246. The author argues that parents need to be free of outside interference in order to be effective in childrearing. *Id.* at 248. The author states, "[w]ithout privacy the family could not express and practice its particular and unique values and ideas; without privacy parents could not foster in themselves or their children those basic human qualities of trust and affection that facilitate the ability to engage in deep and important social relationships both within the family and outside of it." *Id.* at 249.

[211] AM. SOC'Y OF HUMAN GENETICS, *supra* note 9, at 1237; Hughes & Helling, *supra* note 9, at 227-228; Koocher, *supra* note 9; King & Churchill, *supra* note 9, at 719; Weithorn, *supra* note 9.

[212] NATIONAL COMMISSION, *supra* note 109, at 130.

[213] *Id.* (stating that "[w]hen parental permission cannot be relied upon as a protective mechanism..., alternative mechanisms should be set in place to protect the health and welfare of the children.").

[214] Redding, *supra* note 10.

interest between parents and children have been recognized by the courts in a variety of contexts.[215] In the area of mental health treatment, parents may often act contrary to a child's best interests.[216] For instance, parents may hospitalize their children in service of their own ulterior motives.[217] This occurred in the case of a seven-year-old girl, with no evidence of a mental disorder, whose parents hospitalized her in a locked psychiatric ward because they disapproved of her older boyfriend.[218] In addition, parents may overmedicate their child to avoid coping with the child's difficult behavior[219] or seek psychotherapy for their child who fails to conform to the parents' unreasonable standards or expectations. [220] When

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[215] State v. Wedige, 289 N.W.2d 538 (1980). Parental rights of natural mother were terminated after a court finding that minor children were within statutory classification of "neglected children." *Id.*; In re Sappington, 704 N.E.2d 339 (1997). A father represented his son in juvenile proceedings, persuading the son to act in a manner that may have been against the minor's interests. *Id.* Appellate court found reversible error in the juvenile court's failure to appoint guardian ad litem for juvenile when there was a strong possibility of a conflict of interest between father and son. *Id.* at 341; In the Interest of Tamela Pernishek, 408 A.2d 872 (1979). The court found a minor qualified as a "dependent," which is defined as a child who is without proper parental care and control, and ordered the placement of the child who was diagnosed as a psychosocial dwarf in a home for crippled children over the objections of her parents. *Id.*; In the Matter of Cabrera, 552 A.2d 1114 (1989). The court ordered blood transfusions over the parents' religious objections. *Id.*; Curran v. Bosze, 566 N.E.2d 1319 (1990). The court refused the father's request to order testing to determine whether minor twins were bone marrow match for the minors' half sibling. *Id.* The court determined that the doctrine of substituted judgment, allowing a guardian to make decisions on behalf of an incompetent based on the incompetent's attitudes, could not be applied in the present case. *Id.* at 1326. The preferences of the twins, who were three and one-half years old, could not be determined, as their value system had not yet been developed. *Id.* at 1326. The court held that "a parent or guardian may give consent on behalf of a minor daughter or son for the child to donate bone marrow to a sibling, only when to do so would be in the minor's best interest." *Id.* at 1331.

[216] *See generally* Redding, *supra* note 10. (arguing that parents do not always act in the child's best interests and proposes that consequently children need to be given a voice in their own mental health decisions in order to protect their due process rights.). See *id.* for full discussion and case examples in the areas of civil commitment, outpatient psychotherapy and outpatient treatment with medication.

[217] *Id.* at 698 (citing Holly Metz, Branding Juveniles Against Their Will, STUDENT LAWYER, Feb. 1992, at 21, 22).

[218] *Id.*

[219] *See id.* at 699. Redding provides an example from his own experience as a clinical psychologist in which, "[t]he mother of a retarded girl gave her about four times her prescribed dose of lithium, a potentially lethal dosage. The mother did this hoping it would sedate her so that the mother would not have to cope with her troublesome behaviors." *Id.*

[220] *See id.* (citing Gerald P. Koocher, Competence to Consent: Psychotherapy, in CHILDREN'S COMPETENCE TO CONSENT 111, 123 (Gary S. Melton et al. eds., 1983)). Redding provides an example of parents of a nine-year-old girl who were members of a

making medical treatment decisions for critically ill children, parents may be influenced by a variety of conflicting priorities, including financial, emotional, marital or family cohesiveness or the interests of their other children.[221] In addition, the emotional distress involved in coping with a seriously ill child may hinder a parent's ability to make fully informed and thoughtful healthcare decisions.[222] Such stress may also interfere with a parents' ability to give permission for their seriously ill child's participation in nontherapeutic research.[223]

An area where a parent-child conflict of interest is easily demonstrated, lies in the context of bone marrow and organ donation by minors.[224] In such cases, minors undergo invasive medical procedures that offer no benefit to themselves, but rather offer a direct benefit to another.[225] As child bone marrow donors frequently donate to biological siblings,[226] parents are faced with the decision of placing one child at risk[227] in the hopes of saving the life of their chronically ill

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fundamentalist religious group and sought therapy for their daughter because "she wore pants, contradicted her parents in conversations, did not sit still in church, and had been associating with the 'wrong crowd.' She had no disciplinary problems at school, however, and was doing well academically. A psychological evaluation was within normal limits." *Id.*

221 King & Churchill, *supra* note 9, at 720.

222 Laura Weiss Roberts, *Informed Consent and the Capacity for Voluntarism*, 159 AM J. OF PSYCHIATRY 705, 706 (explaining that the emotional distress experienced by the parent of a dying child may create a barrier to voluntarism, which is a critical element in truly informed consent).

223 JAY KATZ, EXPERIMENTATION WITH HUMAN BEINGS 961 (1972). A case is described in which a terminally ill child's mother gave consent for the child to participate in studies that would serve no benefit to the child and would subject the child to severe stress. *Id.* The mother stated that by allowing her child to participate, the child's life will have at least been worthwhile. *Id* Her consent was viewed as a reaction to her severe psychological stress, and served to deal with and justify the child's imminent death. *Id.*

224 NATIONAL COMMISSION, *supra* note 109, at 80.

225 *Id.*

226 Wendy Packman, et al., *Psychosocial Consequences of Bone Marrow Transplantation in Donor and Nondonor Siblings*, 18 J. DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS 244, 244 (1997) (stating that approximately 76% of pediatric patients receiving bone marrow transplants receive marrow from a sibling).

227 *See* id. The authors conducted a study investigating the psychosocial consequences of bone marrow transplantation in both the donor sibling as well as other siblings in the family who were not chosen as donors. *Id.* Results showed adverse effects on both donor and nondonor siblings. *Id.* at 251. Sibling donors suffered from more anxiety and lower self-esteem than did nondonors. *Id.* One third of both donors and nondonors suffered from moderate to severe symptoms of post-traumatic stress. *Id.*; *see also* Linda Z. Abramovitz, *Perspectives on Pediatric Bone Marrow Transplantation, in* BONE MARROW TRANSPLANTATION: PRINCIPLES, PRACTICE, AND

child.[228] When placed in this dilemma, the needs of the ill child may interfere with the parents' consideration of the best interests of the potential donor sibling child.[229]

A controversial issue directly within the scope of scientific research and parent-child conflict of interest involves compensation offered for participation in pediatric research.[230] Opportunities for financial gain may distort parental decision-making in favor of parental agreement to enroll children in research that is contrary to the children's interests. [231] Payments may lead parents to intentionally ignore risks and enroll their children in order to reap the monetary benefits,[232] or to keep their children enrolled in a study even when risks to the child develop.[233] In addition, payments may lead parents to unconsciously minimize risks and exaggerate benefits of the research.[234]

B. THE CASE OF UNINFORMED INFORMED CONSENT

Evidence suggests that informed consent procedures have failed to provide potential research participants with the information necessary to make reasonably intelligent and informed decisions regarding participation in scientific research.[235] The Regulations outline specific requirements for informed consent in scientific research,[236] all of which must be

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NURSING INSIGHTS 70, 75 (Marie Bakitas Whedon ed., 1991) (stating that physical risks to a donor include general anesthesia, bleeding, infection and postoperative pain.).

[228] Victoria Weisz, *Psycholegal Issues in Sibling Bone Marrow Donation*, 2 ETHICS & BEHAVIOR 185, 186 (1992).

[229] *Id.* (explaining that the needs of the ill child interferes with the parents' consideration of the needs of the donor child); Abramovitz, *supra* note 227, at 74-75. The increased levels of anxiety and stress for the parents of a child needing a bone marrow transplant often prevents them from effectively hearing and comprehending the information provided to them, which then affects their decision-making process. *Id.* The author also recognizes the conflict of interest that arises when parents give consent for one of their children to give marrow and the other to receive it. *Id.* at 74. See Curran v. Bosze 566 N.E.2d 1319 (1990) for court analysis of parental rights in consenting to child bone marrow donation.

[230] *See* David Wendler, et. al., *The Ethics of Paying for Children's Participation in Research*, 141 J. PEDIATRICS 166 (2002) (discussing the controversy of paying for children's participation in research and the ethical concerns it provokes).

[231] *Id.* at 166.

[232] *Id.*

[233] *Id.* at 169.

[234] *Id.* at 166.

[235] Tarnowski, *supra* note 11.

[236] 45 C.F.R. § 46.116(a), (b) (1994). See *infra* Part I.C. for discussion of the

presented in language understandable to the potential participant.[237] Ethical codes applicable to scientific research further stress the necessity of participant comprehension in the informed consent process.[238] Despite these legal and ethical requirements, studies have consistently demonstrated that the readability of informed consent forms may be beyond the understanding of the average research participant.[239] Grundner's 1980 study on the readability of consent forms indicated that comprehension of a wide variety of hospital consent forms required an undergraduate or graduate reading level.[240] In a study by Baker and Taub in 1983, consent forms and information used for medical research in a Veterans Administration Medical Center were found to require a college-level reading ability.[241] In 1990, Tarnowski's study of all informed consent forms submitted to the Human Subjects Institutional Review Board of one of the largest pediatric

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statutory requirements of informed consent.

[237] 45 C.F.R. § 46.116 (1994).

[238] Nuremberg Code, *supra* note 1, principal 1; BELMONT REPORT, *supra* note 2, at Part C. The Report identifies comprehension as a necessary element of informed consent: "The manner and context in which information is conveyed is as important as the information itself.... Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information." *Id.*; AMERICAN PSYCHOLOGICAL ASSOCIATION, ETHICAL PRINCIPALS OF PSYCHOLOGISTS AND CODE OF CONDUCT 6.11(a). "Psychologists use language that is reasonably understandable to research participants in obtaining their appropriate informed consent." *Id.*

[239] *See, e.g.,* Grundner, *supra* note 11; Tarnowski, *supra* note 11; Baker & Taub, *supra* note 11.

[240] Grundner, *supra* note 11, at 901. Grundner included the consent forms from five medical facilities in the Los Angeles area, each representing a different type of facility. *Id.* The Fry Readability Scale and the Flesch Readability Formula, based on syllable count and sentence length, were used to determine scores. *Id.* Scores on the Fry Readability Scale corresponds to grade-level equivalencies. *Id.* Scores on the Flesch Readability Formula correspond to one of seven categories of scores, which range from "very difficult" to "very easy," and also describes the type of reading material generally found in each category, ranging from "scientific journals" to "comic books." *Id.* Flesch scores range from 1 to 100, with a lower score representing an easier reading level. *Id.* Grundner suggests that adult consent forms should be at a maximum of a seventh or eight grade level, corresponding to 60 to 70 Flesch readability scores. *Id.* All consent forms in the study scored under 15, with one form with a round score of 37. *Id.*

[241] Baker & Taub, *supra* note 11, at 2647. Baker & Taub use the Flesch Readability Formula described *supra* note 186. *Id.* Baker & Taub found a mean score of less than 50 for the information sheets and less than 40 for consent forms, corresponding to college-level reading skills. *Id.* In addition, all forms were found to increase in length over time, which may have affected the overall difficult level of the information materials. *Id.* at 2647-2648.

hospitals in the United States revealed that informed consent forms for pediatric biomedical research were written at a graduate reading level.[242] Studies investigating the readability of informed consent forms have documented the failure of forms to provide participants with information in language they can easily comprehend.[243] Given the vulnerability of children and the responsibility of parents to make an informed decision on behalf of their children, the results of Tarnowski's pediatric research study raises major concerns.[244] The requirement of an inappropriately high reading ability in the comprehension of informed consent forms is even more problematic in research involving children since the data suggests that parents who volunteer their children for clinical research may be less educated and less represented in professional occupations.[245] Such findings indicate the need to take particular vulnerabilities of parents into account when obtaining parental permission in pediatric research.[246]

Informed consent may be further compromised by the "therapeutic misconception."[247] The phenomenon of the therapeutic misconception, seen in the medical setting, occurs when patients assume that they are asked to enroll in research

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[242] Tarnowski, *supra* note 11, at 59-60. Tarnowski uses the Flesch Readability Formula and the Fry Readability Scale described *supra* note 186. *Id.* at 59. The results showed a mean Flesch Reading Ease Score of 26.91 and a Fry grade equivalent of 16.24, both corresponding to graduate school reading levels. *Id.* The length of the consent form was also found to have increased dramatically over time, containing approximately 25 printed lines in 1978 and nearly 100 printed lines by 1987. *Id.* at 60.

[243] *See, e.g.*, Lehrman & Sharav, *supra* note 18, at 230 (stating that research shows that informed consent forms are difficult to comprehend and specifically citing a study by Ogloff and Otto (J. R. P. Ogloff & R. K. Otto, *Are Research Participants Truly Informed? Readability of Informed Consent Forms Used in Research*, 1 ETHICS & BEHAVIOR 239 (1991)) which found that informed consent forms were written at an unreasonably high reading level and participants were therefore most likely not adequately informed about the studies they participated in); Tarnowski, *supra* note 11, at 61.

[244] Tarnowski, *supra* note 11, at 60.

[245] S.C. Harth, R. R. Johnstone, & Y. H. Thong, *The Psychological Profile of Parents Who Volunteer their Children for Clinical Research: A Controlled Study*, 18 J. MED. ETHICS 86, 90 (1992).

[246] *Id.* at 92; *see also Id.* at 90 (citing W.A. Silverman, *The Myth of Informed Consent: In Daily Practice or in Clinical Trials*, 299 J. MED. ETHICS 251 (1989) who endorsed the idea of a social filter that selects for participation in research, "those who do not understand, those too frightened to refuse, those who are socially disadvantaged.").

[247] Pritchard, *supra* note 13, at 6 (citing P. Appelbaum, et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 2, HASTINGS CENTER REP., 20 (1987)).

for their own benefit rather than nontherapeutic research purposes.[248] Furthermore, they may have unrealistic expectations about potential benefits of the experiment[249] and the risks they may incur as research participants. [250] The therapeutic misconception may especially occur when clinicians take on the dual role of researcher and recruit their own patients to participate in research projects.[251] Rather than understanding that the focus of the research is the pursuit of knowledge, patients may view their physician's invitation to be involved in the research as "a professional recommendation."[252] The participants may be misled by the dual status of the clinician researcher, as well as their own hope for beneficial treatment.[253]

In the educational context, in which parental permission is sought for research with school children, the dual status of teachers as researchers may create a similar misunderstanding.[254] The "educational misconception"[255] occurs when both parents and students falsely assume that teachers conducting research are inviting students to participate because of the educational value of the research.[256]

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[248] *Id.*; *see also* DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, INSTITUTIONAL REVIEW BOARDS: THEIR ROLE IN REVIEWING APPROVED RESEARCH, 4, *at* http://oig.hhs.gov/oei/reports/oei-01-97-00190.pdf [hereinafter ROLE IN REVIEWING APPROVED RESEARCH].

[249] Frances H. Miller, *Trusting Doctors: Tricky Business When it Comes to Clinical Research*, 81 B.U.L. REV. 423, 432 (2001) (stating, "Most seriously ill patients do not want to acknowledge that a clinical trial will probably not help their condition. Instead, these desperate souls want to believe in the omnipotence of medicine."); ROLE IN REVIEWING APPROVED RESEARCH, *supra* note 248, at 4.

[250] ROLE IN REVIEWING APPROVED RESEARCH, *supra* note 248, at 4.

[251] Pritchard, *supra* note 13, at 6 (citing P. Appelbaum, et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 2, HASTINGS CENTER REP., 20 (1987)).

[252] Tuthill, *supra* note 13, at 224.

[253] Pritchard, *supra* note 13, at 6 (citing P. Appelbaum, et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 2, HASTINGS CENTER REP., 20 (1987)); DEPARTMENT OF HEALTH AND HUMAN SERVICES, *supra* note 248, at 5. Individuals may not even distinguish between research and treatment. *Id.* A survey of 1,882 randomly selected patients of whom 371 had been research subjects, showed that 20% incorrectly stated that they had never been involved as research subjects. *Id.* In addition, 40% of the studies involving these patients carried greater than minimal risk. *Id.* Blurring the distinction between research and treatment may be caused by researchers who emphasize the benefits of research and recruit their own patients for research. *Id.*

[254] Pritchard, *supra* note 13, at 6.

[255] *Id.*

[256] *Id.*

The researcher's priority, however, is the pursuit of knowledge rather than the welfare of the students.[257] This assumption may apply in various other contexts as well, where a practitioner assumes the dual role of a researcher.[258] When such misconceptions are operating, true informed consent may be questionable.[259] The various inadequacies of informed consent discussed above should provoke serious questions as to whether parents may unintentionally make uninformed decisions when permitting their children to participate in scientific research.

IV. CAN INSTITUTIONAL REVIEW BOARDS SUCCEED WHEN PARENTS FAIL?

All research subject to the federal regulations must be reviewed and approved by the IRB of the institution at which the research is being conducted.[260] The principal goal of an IRB is to protect the rights of human research participants.[261] When children are involved in research, the IRB has the additional responsibility of enforcing the special safeguards enacted to protect child participants.[262] The ability of IRBs to adequately protect research participants, however, has been widely criticized.[263] Considering that "[t]he effectiveness of IRBs is in jeopardy,"[264] relying on IRBs to effectively protect children may be misguided. Furthermore, the inadequacies of IRBs may consequently jeopardize the federal system's effectiveness in safeguarding research.[265]

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257 *Id.*

258 *Id.*

259 *Id.* at 5-6; *see also* ROLE IN REVIEWING APPROVED RESEARCH, *supra* note 248, at 4.

260 45 C.F.R. § 46.103(b) (1994).

261 F. Richard Ferraro, Laurie Orvedal & Joseph J. Plaud, *Institutional Review Board Issues Related to Special Populations*, 125 J. GEN. PSYCHOL. 156, 156 (1998).

262 45 C.F.R. § 46.111(b) (1994); 45 C.F.R. § 46.403 (1994).

263 *E.g.*, Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L. J. 7, 9 (1993); Hazel Glenn Beh, *The Role of Institutional Review Boards in Protecting Human Subjects: Are We Really Ready to Fix a Broken System?*, 26 LAW & PSYCHOL. REV. 1, 34 (2002); Michael Baram, *Marking Clinical Trials Safer for Human Subjects*, 27 AM. J. L. & MED. 253, 267-268; Pritchard, *supra* note 13, at 7-8.

264 DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM, 4, *at* http://oig.hhs.gov/oei/reports/oei-01-97-00193.pdf [hereinafter TIME FOR REFORM].

265 Beh, *supra* note 263, at 34.

A. INSTITUTIONAL REVIEW BOARD EVALUATIONS

The Regulations outline several requirements for IRB evaluation, which must be met before an IRB may approve research activities.[266] First, research procedures must minimize risks to participants.[267] Second, risks to participants must be reasonable in comparison to anticipated benefits.[268] Third, selection of research participants must be equitable to avoid unnecessary inclusion of vulnerable populations.[269] Fourth, informed consent must be appropriately sought and documented.[270] Fifth, adequate provisions must exist to monitor data collection to ensure safety of participants during the course of the research.[271] Finally, adequate provisions must be in effect to protect the privacy and confidentiality of participants.[272] In research involving children, additional safeguards must be included.[273] Furthermore, conditions imposed by the Regulations' special protections for children must be satisfied.[274]

To ensure a comprehensive and balanced evaluation of research activities, an IRB must include at least five members with various backgrounds and qualifications.[275] Diversity should be accomplished through consideration of members' professions,[276] race, gender and cultural background.[277] The

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266 45 C.F.R. § 46.111 (1994).

267 45 C.F.R. § 46.111(a)(1) (1994).

268 45 C.F.R. § 46.111(a)(2) (1994); Donald F. Phillips, *Institutional Review Boards Under Stress: Will They Explode or Change?*, 276, JAMA, 1623, 1623 (1996). "Risks can be classified as physical, psychological, social, or economic, and are defined in terms of probabilities or magnitude of harm or discomfort. Benefits are defined as providing new knowledge or improving the health of the subject." *Id.*

269 45 C.F.R. § 46.111(a)(3) (1994).

270 45 C.F.R. §§ 46.111(a)(4)-(5) (1994).

271 45 C.F.R. § 46.111(a)(6) (1994).

272 45 C.F.R. § 46.111(a)(7) (1994).

273 45 C.F.R. § 46.111(b) (1994).

274 45 C.F.R. § 46.403 (1994). See discussion *infra* Part I.C. of statutory requirements of research involving children.

275 45 C.F.R. § 46.107 (1994).

276 45 C.F.R. § 46.107(b) (1994) ("No IRB may consist entirely of members of one profession.").

277 45 C.F.R. § 46.107(a) (1994) ("The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds...."); 45 C.F.R. § 46.107(b) (1994) ("Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis

Regulations attempt to prevent biased evaluations by excluding members with conflicting interests from participation in any initial or continuing reviews of the particular research project.[278] Impartial evaluations are further encouraged by the mandatory inclusion of a member not affiliated with the institution,[279] as well as a member whose areas of concern are nonscientific in nature.[280] In spite of efforts to secure objective review and therefore ensure protection of research participants, such efforts may be undermined by the competing interests of the researchers and the institution.[281] Of all the interests involved in an IRB review, those of the research participants may be least protected.[282]

B. INTERESTS CONFLICTING WITH PROTECTION OF HUMAN RESEARCH PARTICIPANTS

1. Researchers

Rejecting research proposals may expose IRBs to legal liability.[283] Aggrieved researchers may sue an IRB for breach of contractual good faith, violation of the researcher's First Amendment "academic freedom" rights, or violation of rights guaranteed under Fourteenth Amendment procedural due process.[284] Therefore, in marginal cases, IRBs may be pressured to sway in favor of researchers and approve questionable or problematic research. IRBs may also be prone to bias towards researchers out of loyalty to their fellow colleagues.[285] IRBs are mostly composed of faculty from the

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of gender.").

278 45 C.F.R. § 46.107(e) (1994) ("No IRB may have a member participate in the IRB's initial or continuing review of any project, in which the member has a conflicting interest, except to provide information requested by the IRB.").

279 45 C.F.R. § 46.107(d) (1994) ("Each IRB shall include at least one member, who is not otherwise affiliated with the institution, and who is not part of the immediate family of a person who is affiliated with the institution.")

280 45 C.F.R. § 46.107(c) (1994) ("Each IRB shall include at least one member whose primary concerns are in scientific areas, and at least one member whose primary concerns are in nonscientific areas.")

281 Moore, *supra* note 13, at 12; Tuthill, *supra* note 13, at 233.

282 Tuthill, *supra* note 13, at 233; *see also* Lehrman & Sharav, *supra* note 18, at 243.

283 Katerberg, *supra* note 4, at 575-576.

284 *Id.* at 576.

285 Beh, *supra* note 263, at 40-41.

researcher's institution.[286] In response to the observation that IRBs protect the institution and the researcher rather than the research participant,[287] one commentator has stated:

> There is considerable truth to this allegation. The majority of IRB members are on the faculty of the institutions to which the investigators belong. They not only share similar interests and objectives but they also know, when sitting in judgment of a research protocol, that their proposals may soon be subjected to similar scrutiny.[288]

Consequently, when reviewing informed consent procedures, IRBs are not likely to make decisions in favor of protecting research participants when doing so would negatively affect a colleague's research.[289] It has thus been said that, "[t]he fundamental flaw or limitation of IRBs is that it's always been the researchers who are in effect regulating themselves."[290]

2. The Institution

IRBs may be pressured to accommodate the financial interests of their institution.[291] As research is a significant source of income for most institutions,[292] IRBs have an interest in facilitating research in order to obtain necessary funding.[293] The *Grimes*[294] court criticized the Johns Hopkins University IRB involved in the research study, accusing the IRB of helping the researchers get around the federal regulations regarding nontherapeutic research with children to satisfy the informed consent requirement.[295] The court stated, "[a]n IRB's primary

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286 Katz, *supra* note 3, at 40-41.

287 *Id.* at 40 (citing George J. Annas, JUDGING MEDICINE 331 (1988)).

288 *Id* at 40-41.

289 *Id.* at 41; *see also* Lehrman & Sharav, *supra* note 18, at 243 (arguing that IRB members may not give appropriate review to informed consent procedures in "fear of 'embarrassing' colleagues who may sit on grant-awarding committees.").

290 Dale Keiger & Sue De Pasquale, Trial and Tribulations, JOHNS HOPKINS MAgazine, Feb. 2002, at http://www.jhu.edu/~jhumag/0202web/trials.html (last visited on Nov. 11, 2002).

291 Time for Reform, supra note 264, at 7.

292 See id.

293 Beh, supra note 263, at 41.

294 Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 807 (Md. 2001); see infra Part II.B. for full discussion of case.

295 Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 807, 814 (Md. 2001). The IRB suggested to the researchers to change informed consent forms regarding the

role is to assure the safety of human research subjects -- not help researchers avoid safety or health-related requirements."[296]

Although government funding has traditionally been the source of funding for most scientific research, increasing amounts of funding are now coming from private industries and foundations.[297] Commercial funding of research further exacerbates potential conflicts of interest.[298] Sponsors often seek out IRBs that will approve their protocols quickly and according to their own conditions, making it difficult for IRBs to conduct independent and unbiased reviews.[299] To reduce possible prejudice, the federal regulations require an IRB to have at least one member who is unaffiliated with the institution and at least one member who is primarily concerned in nonscientific areas.[300] Despite this requirement, the Office of Inspector General of the Department of Health and Human Services, has found that most IRBs are unable to consistently recruit and maintain laypersons or nonaffiliated members.[301] Since the inclusion of such members is important in keeping IRBs focused on their responsibility of protecting research participants,[302] protection of participants may be compromised.

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control group. Id. A letter from the IRB to the head researcher contained the following: "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." Id.

296 Id.

297 Jesse A. Goldner, Dealing with Conflicts of Interest in Biomedical Research: IRB Oversight as the Next Best Solution to the Abolitionist Approach, 28 J. L., Med., & Ethics 379, 385 (2000); Time for Reform, supra note 264,at 7 (stating that "[a]t the academic health centers we visited, commercial sponsorship accounted for as much as 50% of the research funding.").

298 Time for Reform, supra note 264, at 7; see also Goldner, supra note 298, at 385.

299 Department of Health and Human Services, supra note 264, at 7-8.

300 See supra notes 279-280 and accompanying text.

301 Department of Health and Human Services, supra note 264, at 8.

302 Id. (stating that these members required by the federal regulations play an "active, effective role in helping the IRBs stay focused on their mission of protecting human subjects").

V. STRENGTHENING PROTECTIONS FOR CHILDREN IN RESEARCH

A. CHILD ADVOCATES

Parents are relied upon to make informed decisions in the best interests of their children when giving permission for their child to participate in scientific research.[303] Parents, however, are not necessarily in the best position to make decisions for their children.[304] Potential conflicts of interests between parents and children raise questions about the adequacy of parental permission in protecting children. Additionally, although the primary goal of IRBs is to protect human research participants, conflicts of interest inherent in IRB review, pressures to approve protocols submitted by colleagues, and financial pressures limit the IRB's ability to effectively protect children.

The weaknesses in parental and IRB protection of children necessitates the creation of a child advocacy program for nontherapeutic research. Child advocates have been used in pediatric bone marrow transplantation to address parental conflicts of interests when a healthy child donates marrow to an ill sibling.[305] In one such procedure utilizing child advocates, all potential minor bone marrow donors were assigned a child advocate from the Public Defender's office.[306] The advocate was responsible for investigating the case, with a critical review of informed consent, and made a recommendation to the Administrative Judge of the Family Court, who then gave final approval.[307] A similar process may be effective in the research arena. Under this scheme, a child advocate would be assigned to all nontherapeutic research involving children. The advocate's responsibility would include reviewing potential risks and benefits to the child and the informed consent procedures. The advocate would then give an approval to the institution's IRB, which would then continue with the normal evaluation procedure. The advocate's positive

303 See 45 C.F.R. § 46, Subpart D (1994); see discussion infra Part I.C.
304 See discussion infra Parts III.A-B.
305 See generally Fredric T. Serota, et al., Role of a Child Advocate in the Selection of Donors for Pediatric Bone Marrow Transplantation, 98 Pediatrics 847 (1981).
306 Id. at 847-848 (discussing the program at the Bone Marrow Transplant Unit of Children's Hospital in Philadelphia); Weisz, supra note 228, at 188.
307 Serota, et al., supra note 306, at 847-848.

recommendation should be necessary for IRB approval of the research proposal. The advocate must be unaffiliated with the institution and should have no personal conflicts of interest that would inhibit an unbiased review. Child advocates would help to ensure an unbiased judgment in the review of pediatric research protocols.

B. EDUCATION FOR PARENTS AND IRBS

Scientific research involving potential risks to children may involve complex issues and information not easily comprehended by parents. Indeed, informed consent procedures with research participants have been shown to be ineffective.[308] Children may, therefore, be put at risk when parents are left to make uninformed or uneducated decisions regarding their children's participation in research. Measures should be taken to ensure that parents are adequately informed before giving permission on behalf of their children. Rather than merely requiring parents to sign an informed consent form, federal regulations should require information to be presented in a multi-media format. Information presented in written, oral and visual forms may provide parents with a more thorough understanding of the research and possible effects on their child. Parents with limited education would especially benefit from information presented in formats unaffected by factors such as reading abilities. The National Institute of Health (hereinafter "NIH") uses computer-based training (CBT) to educate IRB members.[309] A similar strategy could be used to educate parents. Information provided should include details regarding the particular research project, as well as information regarding how potential risks may affect a child in the specific stage of development of the children involved in the study. The information could be accessed through the internet with electronic certification when the program is completed.[310]

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308 See Grundner, supra note 11; Baker & Taub, supra note 11. See discussion infra Part III.B of lack of participant comprehension of informed consent forms.

309 Alison Wichman, Protecting Vulnerable Research Subjects: Practical Realities of Institutional Review Board Review and Approval, 1 J. Health Care L. & Pol'y 88, 99-100 (1998).

310 This process is similar to that of the NIH program.

IRBs may actually be contributing to the problems of informed consent. It has been hypothesized that a desensitization process may occur among members of IRBs when evaluating informed consent forms.[311] Repeated exposure to scientific and legal terminology over time may make the complex language more readable.[312] This hypothesis is even more convincing when considering that IRBs consist mostly of physicians and researchers.[313] As a result, complicated or even inappropriate language included in informed consent forms may be approved without objection.[314] Desensitization may be alleviated by objective assessments of the reading level of all informed consent forms. It has been suggested that informed consent forms should not exceed a seventh or eighth grade reading level.[315] Therefore, standards for reading level should be created and enforced for all forms. Rather than relying on subjective evaluation of reading level of forms by IRB members, all forms should be subjected to standardized testing procedures and held to a specific reading level standard.

In addition, although IRBs should have the scientific expertise to evaluate a research project, IRBs may join parents in a lack of informed understanding necessary to make educated reviews.[316] If an IRB is reviewing research outside the scope of expertise of any of its members, the board may simply not have adequate understanding of critical elements of a proposal to evaluate it effectively.[317] In research involving children, an issue such as child risk assessment may require special expertise in child development. Therefore, IRBs should be required to involve a child specialist in approving nontherapeutic research with children. The federal regulations provide that, when IRBs regularly review research involving vulnerable participants such as children, IRBs should give consideration to individuals who have expertise with such potential participants.[318] IRBs should be required to

311 Tarnowski, supra note 11, at 61.
312 Id.
313 Id.
314 Id.
315 Grundner, supra note 11, at 902.
316 Pritchard, supra note 13.
317 Id.
318 45 C.F.R. 46.107(a) (1994) "If an IRB regularly reviews research that involves a

consistently include a child expert, such as a child psychologist or psychiatrist, in all research proposals involving children. The expert should be knowledgeable about child development, including potential physical and psychosocial risks involved in participation in research. Responsibilities of the child expert should also include reviewing informed consent procedures to ensure all necessary information is included. Finally, child assent procedures should be evaluated for proper developmental level and appropriate information.

VI. CONCLUSION

Throughout history, children have been particularly victimized by researchers.[319] Despite attempts to safeguard children, procedures remain ineffective in protecting the rights and welfare of children involved in nontherapeutic research. Current law provides children with protective mechanisms through federal regulations applying specifically to children. Under the assumption that parents are a natural safeguard for children, the Regulations give parents the right to make decisions that will be most beneficial to their children. As an additional layer of protection, the Regulations have assigned IRBs the task of reviewing and approving research proposals and enforcing the Regulations' guidelines for human participant safety. Trust in these two methods of protection alone places vulnerable children at great risk of harm when participating in nontherapeutic research. This Comment has addressed the inherent weaknesses of reliance on both of these safeguards and has proposed potential remedies. Child advocates will help ensure an objective review of research involving children. Additional educational resources for both parents and IRBs will allow for a more informed decision-making process. Finally, mandatory inclusion of child experts on IRBs in the evaluation of all research proposals involving children is necessary to ensure a knowledgeable evaluation. These measures go beyond current protective mechanisms and

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vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects." Id.

319 Glantz, supra note 5, at 215.

would help alleviate the problems inherent in the misguided trust we have placed on parents and institutions to protect children in nontherapeutic research.

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