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**Current Issues In Public
Policy**





**WORD FROM THE ACADEMIES:
A PRIMER FOR LEGAL POLICY ANALYSIS
REGARDING ADOLESCENT RESEARCH
PARTICIPATION**

Rhonda Gay Hartman*

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I. INTRODUCTION

Few voices regarding scientific research are as eminent as the National Academies.¹ When the Academies speak, Congress and the White House not only listen but also act. As federal legislation and executive orders exemplify, the Academies' reports about challenges at the biomedical science-society interface inform public policies and influence laws.² Foremost at this interface are the challenges of human subject experimentation that have not atrophied over time.³ These

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I wish to express my gratitude to the faculty of the Yale Interdisciplinary Bioethics Project for stimulating my thinking about adolescent research participation, and for their helpful comments. I am also grateful to the editors of the Rutgers Journal of Law & Public Policy for their valuable support.

¹ The National Academies include the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council. The National Academies play a prominent role in the furtherance of science and technology for the general welfare by bringing together experts in all areas of science and technology to address critical issues, advise the federal government, and inform public policy. The Academies' influences in actions taken by both Congress and the White House have reaffirmed its prominence in shaping law and policy. See <http://www.nationalacademies.org>.

² See <http://www.nationalacademies.org> for documentation of congressional actions and executive orders that have resulted from the National Academies' legacy for improving the health, education, and welfare of Americans.

³ See, e.g., Edmund D. Pellegrino, *The Nazi Doctors and Nuremberg: Some Moral Lessons Revisited*, 127 ANNALS OF INTERNAL MED. 307, 308 (1997) (extolling "the lessons still to be learned from the Nuremberg Trials...[that] must be repeatedly relearned. They are pertinent to other contexts and other issues in today's intensive bioethics debates."). For a small sampling of the lessons gleaned from past and present human subject studies, see, e.g., Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966); Robert D. Mulford, *Experimentation on Human Beings*, 20 STAN. L. REV. 99 (1967); Donna Shalala, *Protecting Research Subjects—What Must Be Done*, 343 NEW ENG. J. MED. 808 (2000); Robert Steinbrook, *Protecting Research Subjects—The Crisis at Johns Hopkins*, 346 NEW ENG. J. MED. 716 (2002).

challenges are rooted in society's deep conflict between advancing knowledge by using persons for bio-scientific research while preserving human rights and dignity.⁴ Although 'therapeutic' biomedical research (i.e., research conducted with a prospect of direct benefit to the participants) continues to merit scrutiny,⁵ 'non-therapeutic' research (i.e., research conducted for knowledge acquisition without the prospect of direct benefit)⁶ compels it, particularly when the participants constitute a vulnerable cohort with diminished decisional capacity for research involvement such as children,⁷ the elderly,⁸ and the mentally infirm.⁹

⁴ See Guido Calabresi, *Reflections on Medical Experimentation in Humans*, in EXPERIMENTATION WITH HUMAN BEINGS 180-184 (Jay Katz ed., 1992). See also Steinbrook, *supra* note 3, at 716 (explicating the "inherent trade-off between the potential importance of the information that may be gained and the potential risk to the subject").

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

⁶ This research distinction, despite its prevalence, is less than precise. Problematic is that "some of the components of every research protocol are non-therapeutic; when they are all non-therapeutic, use of the term 'non-therapeutic research' might be justified." Robert J. Levine, *International Codes of Research Ethics: Current Controversies and the Future*, 35 IND. L. REV. 557, 559-560 (2002) (critiquing the Declaration of Helsinki and concluding that revisions have not corrected the flawed distinction between therapeutic and non-therapeutic research). See also Loretta M. Kopelman, *What Conditions Justify Risky Nontherapeutic or "No Benefit" Pediatric Studies: A Sliding Scale Analysis*, 32 J.L. MED. & ETHICS 749 (2004) (distinguishing conditions "that, all things being equal, should allow hazard in no benefit or nontherapeutic pediatric studies from those that should not"). *Accord Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 814-815 (Md. 2001).

⁷ See Glantz, *supra* note 5, at 213; Robert J. Levine, *Research Subjects*, in CHILDREN AND HEALTH CARE: MORAL AND SOCIAL ISSUES 73 (Loretta M. Kopelman & John C. Moskop eds., 1989).

⁸ See Marshall B. Kapp, *Decisional Capacity, Older Human Research Subjects, and IRBs: Beyond Forms and Guidelines*, 9 STAN. L. REV. 359 (1998).

⁹ See Alexander Morgan Capron, *Ethical and Human-Rights: Issues in Research on Mental Disorders That May Affect Decision-Making Capacity*, 340 NEW ENG. J. MED. 1430 (1999). See also D.C. CODE ANN. §7-1305.09 (2002).

Of this research cohort, adolescents (fourteen through seventeen years) have received scant attention. The relative inattention stems from conventional suppositions about adolescent vulnerability and decisional incapacity. The law categorizes adolescents among ‘minors’—persons under eighteen who are presumed to lack decisional capabilities.¹⁰ Adolescents have therefore been subsumed under the “child” rubric, whereby parents decide about research participation.¹¹ Although it is not clear whether parental decision making has impeded adolescents’ participation, an emergent need for adolescent research inclusion is now clear. Adolescent participants are crucial to achieving valid, reliable findings concerning drug effects and dosages,¹² in addition to acquiring knowledge about problems particularized to this age group such as HIV infection,¹³ depression,¹⁴ and obesity,¹⁵ to name a few. The complexities and challenges of adolescent research participation are among the most thought provoking in human subject experimentation and yet remain largely unexamined.

¹⁰ See Rhonda Gay Hartman, *Coming of Age: Devising Legislation for Adolescent Medical Decision-Making*, 28 AM. J.L. & MED. 409 (2002).

¹¹ See Protections of Human Subjects, Subpart D—Additional Protections for Children Involved as Research Subjects, 45 C.F.R. §§ 46.401 et seq. (2003).

¹² This includes pharmacokinetic studies that investigate how medications are absorbed and distributed among organs of the body (e.g., the relationship between the dose and concentration of medicine in the blood). See COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, INSTITUTE OF MEDICINE, ETHICAL CONDUCT OF CLINICAL RESEARCH INVOLVING CHILDREN 68-69 (Marilyn J. Field & Richard E. Behrman eds., 2004).

¹³ See generally Rhonda Gay Hartman, *AIDS and Adolescents*, 7 J. HEALTH CARE L. & POL’Y 280 (2004).

¹⁴ See American Academy of Pediatrics, Committee on Adolescence, *Suicide and Suicide Attempts in Adolescents*, 105 PEDIATRICS 871 (2000).

¹⁵ See Karen C. Swallen et al., *Overweight, Obesity, and Health-Related Quality of Life Among Adolescents: The National Longitudinal Study of Adolescent Health*, 115 PEDIATRICS 340 (2005); Thomas H. Inge et al., *Bariatric Surgery for Severely Overweight Adolescents: Concerns and Recommendations*, 114 PEDIATRICS 217 (2004).

The National Academies, through an Institute of Medicine (IOM) report, has thus prioritized research with adolescents.¹⁶ The stated reasons are principally two-fold: to increase adolescents' participation in clinical research, thereby alleviating their longstanding 'therapeutic orphan' status,¹⁷ and to acquire knowledge that enables treatment customization and other benefits.¹⁸ By elucidating a research agenda that differentiates between children and adolescents and also acknowledging the decision-making capacity of mature minors,¹⁹ the IOM's report serves as a primer for developing policy and structuring a legal regime for adolescent research participation apart from mere extrapolation from models designed for children and adults. To this end, the unique issues raised by research with adolescents compel examination.

This Article examines these issues in the context of adolescent non-therapeutic research for law and policy development. Part II discusses the IOM's central objectives within the existing regulatory regime. Part III addresses specific issues for policy development crucial to structuring a legal framework that both protects adolescents' interests and promotes their research involvement. Overarching issues compelling particularized policy consideration include recruitment and consent processes, privacy protections, researchers' roles and responsibilities, and regulatory oversight procedures. Part IV of this Article fleshes out points for policy analysis by framing the questions that invite scientific and social-scientific scrutiny and recommends how the law should proceed in achieving the objectives envisaged by the IOM.

¹⁶ See COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 26.

¹⁷ See Harry Shirkey, *Therapeutic Orphans*, 72 J. PEDIATR. 119, 119-120 (1968); see also COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 58-92.

¹⁸ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 66-74.

¹⁹ *Id.* at 181-186.

II. THE FEDERAL REGULATORY REGIME AND THE IOM'S REPORT

Regulatory oversight of human subject research is generally a function of federal law. Federal regulations were promulgated thirty years ago to oversee the ethical conduct of human subject research.²⁰ The primary purpose was to provide an analytical framework for guiding “the resolution of ethical problems arising from research involving human subjects.”²¹ Then, as now, four basic principles are relevant: respect for persons (individuals should be treated as autonomous agents and those with diminished autonomy are entitled to protection); beneficence (maximize benefits while minimizing harms); nonmaleficence (the maxim of ‘do no harm’); and justice (access to research participation and receipt of its benefits and burdens).²²

Additional regulations were promulgated in 1983 to protect children participating in research primarily from exploitation, misuse, and abuse.²³ Specifically, these regulations focus on parental consent procedures and oversight by specially constituted institutional review boards (IRB).²⁴ The regulations require parental consent for a child’s participation in non-therapeutic research, accompanied by the child’s assent,²⁵

²⁰ See Protections for Children, *supra* note 11, at §§ 46.101-46.124; see also THE NAT’L COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, NAT’L INSTITUTES OF HEALTH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979). For commentary and critique of the regulations, see Glantz, *supra* note 5, at 213-218; ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 321-325 (2d ed. 1988).

²¹ THE BELMONT REPORT, *supra* note 20, at 3.

²² *Id.* at 3-5.

²³ Protections for Children, *supra* note 11, at §§ 46.401-409. See COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 102; Glantz, *supra* note 5, at 224.

²⁴ Protections for Children, *supra* note 11, at §§ 46.403-408. See Glantz, *supra* note 5, at 213; LEVINE, *supra* note 20.

²⁵ Protections for Children, *supra* note 11, at §§ 46.406-408.

unless the IRB delineates a basis for waiving the parental consent requirement.²⁶ The reasons behind the requirement for adolescent assent, rather than autonomy, are unarticulated.

The IRB is further responsible for reviewing and approving research protocols using child subjects to determine tolerable risks and how the risks should be balanced against the prospect for knowledge acquisition.²⁷ Under the regulations, IRBs may approve children's participation in non-therapeutic research involving either minimal or slightly more than minimal risk.²⁸ Should the risk potential exceed minimal or a minor increase over minimal risk—that reasonably commensurate with medical, dental, psychological, social, or educational experiences—approval is contingent on review by a panel convened by the Department of Health and Human Services (DHHS).²⁹ This panel is to determine that the research will: present reasonable opportunities for furthering the understanding, prevention, or alleviation of a serious health or welfare problem afflicting minors despite known or predictable risks; proceed in accordance with ethical principles; and provide for soliciting both parent or guardian permission and the child participant's assent.³⁰ Referrals to DHHS under this regulatory provision now include a public review and comment process.³¹

Underlying those regulatory protections for children are bifurcated aims of safeguarding minors' best interests while yielding generalized knowledge about drug therapies and other

²⁶ *Id.* at § 46.408 (c).

²⁷ *Id.* at §§ 46.403-408.

²⁸ *Id.* at § 46.406. See David Wendler & Ezekiel J. Emanuel, *What is a "Minor" Increase Over Minimal Risk?*, 147 J. PEDIATR. 576 (2005) (discussing various standards for defining degrees of risk within meaning of the regulations).

²⁹ *Id.* at § 46.407 (a) & (b).

³⁰ *Id.* at § 46.407 (b) (1) & (2)(i)-(iii).

³¹ Examples of research proposals that prompt review under Section 46.407 include study of sleep mechanisms with children or a diluted smallpox vaccine in children. See COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 55.

medical treatments beneficial to younger age groups. Subsequent federal research policies emphasize increased research access given the need for therapies tailored to minors' health problems,³² particularly drug testing to determine effects at various developmental stages and proper dosages.³³ For example, the Pediatric Research Equity Act of 2003 authorizes the Food and Drug Administration to require pediatric studies of specific drugs and biological products rather than extrapolate data from studies with adults.³⁴ Most research conducted with children is funded or supported by federal agencies such as the National Institutes of Health, and the Children's Health Act mandates compliance with the regulations.³⁵ Privately supported research need only comply with state regulatory schemes and institutional requirements.

Despite regulatory modifications geared to upgrading safeguards and enhancing the ethical conduct of research with children, the federal regulations have scarcely been revised, much less reconfigured, to address adolescent research participation and the distinct considerations thereto. The federal regulations discern the definition of children from state law.³⁶ State law defines children as persons less than eighteen years and disallows their decisional autonomy, subject only to court-ordered emancipation or statutory allowances for decision making about certain conditions (e.g., sexually transmitted

³² For a discussion of these policies, see Lainie Friedman Ross, *Children in Medical Research: Balancing Protection and Access—Has the Pendulum Swung Too Far?* 47 PERSPECTIVES ON BIO. & MED. 519 (2004); COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 54-57, 105-110, 216-217.

³³ 21 U.S.C. §§ 301 et seq. (2003).

³⁴ *Id.*; 21 C.F.R. §50.50-56 (2003).

³⁵ 42 U.S.C. §§ 2101 et seq. (2000); Protections for Children, *supra* note 11, at § 46.401.

³⁶ Protections for Children, *supra* note 11, at § 46.402 (a).

disease)³⁷ or in certain circumstances (e.g., independent living).³⁸ Other than statutes or court-ordered emancipation recognizing minors' legal autonomy, state law uniformly presumes decisional incapacity of minors, whether six or sixteen.³⁹ The federal regulatory regime thus applies to all minors uniformly, regardless of their decision-making capability.⁴⁰

Federal regulatory reliance on the amalgam of statutory bases that affords legal autonomy to adolescents largely results in a patchwork of interpretation by IRBs.⁴¹ For non-therapeutic research participation, the regulations require parental consent and adolescent assent, unless an IRB determines that parental consent should be waived.⁴² In contrast, the IOM recommends that decisionally capable adolescents, rather than their parents, should provide the consent for research involvement.⁴³ Although professional organizations such as the Society of Adolescent Medicine endorse decisional autonomy in its published guidelines for ethically conducting research with adolescents,⁴⁴ those guidelines neither address how increased

³⁷ See, e.g., PA. STAT. ANN. tit. 35 § 521.14a (West 2005); VA. CODE ANN. § 54.1-2969 (E)(1) (Michie 2005).

³⁸ See, e.g., ME. REV. STAT. ANN. tit. 22, § 1503 (West 1992 & Supp. 2004); MINN. STAT. ANN. § 144.341 (West 2004).

³⁹ For analysis of state legislation regarding adolescent medical decision making, see Hartman, *supra* note 10, at 409-410, 416-427.

⁴⁰ See Glantz, *supra* note 5, at 213.

⁴¹ See Audrey Smith Rogers et al., *Adolescent Participation in Clinical Research: Eleven Sites, One Common Protocol, and Eleven IRBs*, 21 IRB 6, 7-10 (1999). See also Kathleen A. Mammel & David W. Kaplan, *Research Consents by Adolescent Minors and Institutional Review Boards*, 17 J. ADOLESC. HEALTH 323, 324-330 (1995) (uncovering a broad spectrum of IRB interpretations).

⁴² Protections for Children, *supra* note 11, at § 46.408 (c). See also *infra* notes 100-101 and accompanying text.

⁴³ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 181-186.

⁴⁴ John S. Santelli et al., *Society for Adolescent Medicine: Guidelines for Adolescent Health Research: Position Paper*, 33 J. ADOLESC. HEALTH 396

inclusion of adolescents in non-therapeutic research can be achieved nor elaborate on the issues germane to this goal.

Supplementary, concurrent state regulation of adolescent research participation, moreover, is virtually nonexistent. States could proactively promote the IOM's aims by enacting legislation that reflects a research policy resulting from consideration of the relevant issues that include adolescent decisional autonomy for non-therapeutic research participation. Scant statutory law addressing research participation concentrates on coverage of research-related costs,⁴⁵ or authorizes research with adolescents in accordance with the federal regulations,⁴⁶ which fail to differentiate concerns particularized to adolescent participation and paradoxically rely on state law.⁴⁷

Failure to differentiate adolescents from children counteracts the IOM's central theme of increasing adolescent research participation. This is emphasized when IRBs interpret and implement parent consent-minor assent requirements as well as risk determinants that vary considerably among institutions.⁴⁸ Subjugating an adolescent to a secondary role of agreeing to the parent's decision disadvantages adolescents' developing cognitive abilities by vitiating benefits that are derived from independent decision making about research participation in which the adolescent, not the parent, has a stake.⁴⁹

(2003); *Code of Research Ethics: A Position Paper of the Society of Adolescent Medicine*, 24 J. ADOLESC. HEALTH 277 (1999).

⁴⁵ See, e.g., CAL. HEALTH & SAFETY CODE § 1370.6 (West 2005); N.Y. INS. LAW § 4900 et seq. (Gould 2005).

⁴⁶ See, e.g., KAN. STAT. ANN. § 65-4974 (a) (2005); MISS. CODE ANN. § 41-41-17 (2) (West 2005); N.Y. PUB. HEALTH LAW § 2444 (McKinney 2005).

⁴⁷ See *Protections for Children*, *supra* note 11, at § 46.402 (a).

⁴⁸ See Rogers et al., *supra* note 41, at 7-10; Mammel & Kaplan, *supra* note 41, at 325-330.

⁴⁹ See also Gideon Koren et al., *Maturity of Children to Consent to Medical Research: The Babysitter Test*, 19 J. MED. ETHICS 142, 144, 147 (1993) (finding that "adults in general accept children to be mature enough to supervise younger children in extremely dangerous situations, the same children are

Requiring an adolescent's acquiescence to a parent's decision (rather than vice versa) results from a social and political construct grounded in "distorted developmental reality" rather than scientific approximation of developmental capabilities.⁵⁰ This construct perpetuates underlying assumptions about adolescents' maturity that are strikingly incongruent with societal notions about acceptable risks arising from adolescents exercising autonomy for other activities.⁵¹ According to several researchers, the inconsistencies and discrepancies embedded in this construct are best illustrated by babysitting, whereby a minor "who is not deemed by society to be mature enough to consent to medical research....is deemed able to make very skilled and difficult decisions on behalf of another individual [e.g. infants or young children]."⁵² For adolescents, the risk may be the unsubstantiated obstacle to research participation and the concomitant loss of substantial benefits.⁵³

Furthermore, degrees of research-related risks for adolescents versus children vary considerably. Both the nature and scope of some risks are likely aberrational or nonexistent with adolescents. Conversely, there are risks attendant to health-related problems such as sexual activity⁵⁴ or substance

judged to be too immature to consent to research" and urging re-evaluation of societal views on minors' participation in the consent process for research).

⁵⁰ See Elizabeth Scott, *The Changing Legal Construction of Adolescence*, 29 HOFSTRA L. REV. 547, 558-564 (2000).

⁵¹ See Koren et al., *supra* note 49, at 142 (concluding that, by not recognizing adolescent consent to research participation, regulatory requirements "may be divorced from reality, and as a result, deprive minors of important rights").

⁵² See *id.* at 147 (detailing the decision-making skills involved in babysitting such as "dealing with emergency situations, seemingly much more complicated and demanding, involving not only themselves but also another child, younger and more helpless than themselves").

⁵³ See THE BELMONT REPORT, *supra* note 20, at 7.

⁵⁴ See Nancy Findholt & Linda C. Robrecht, *Legal and Ethical Considerations in Research with Sexually Active Adolescents: The Requirement to Report Statutory Rape*, 34 PERSPECTIVES ON SEX & REPRO. HEALTH 259 (2002); Abigail English, *Runaway and Street Youth at Risk for*

use⁵⁵ endemic to adolescents rather than to children. Additionally, adolescents are more likely than children to be sensitive to being singled out by social or economic class, race, or ethnicity for study.⁵⁶ Because the existing regulations insufficiently define risk in the realm of adolescence, courts are in disarray when interpreting regulatory language.⁵⁷ It is also not sensible to expect courts to develop policies governing adolescent subject research—or to think sensibly that they have any expertise to do so.

Thus, this task must not be deferred to judicial guidance based on reactionary responses to specific circumstances and claims raised by litigants. Rather, a proactive comprehensive policy approach to increasing adolescent research participation is required. This approach must reflect finely-grained inquiry and empirical investigation of the relevant issues in order to drive regulatory reform, state statutory enactments, or a combination thereof in the direction of the IOM's objectives. Indeed, the IOM's report underscores that issues in human subject research should be seen and studied in a different light, one that illuminates concerns germane to adolescence.⁵⁸

III. LEGAL POLICY ANALYSIS FOR INCREASING ADOLESCENT RESEARCH INVOLVEMENT

Framing issues for empirical investigation and policy analysis is critical for catalyzing a legal scheme that implements the IOM's aims for increasing adolescents' participation in non-therapeutic biomedical research. To this end, a threshold task is

HIV Infection: Legal and Ethical Issues in Access to Care, 12 J. ADOLESC. HEALTH 504 (1991).

⁵⁵ See J. D. Caskey & Susan L. Rosenthal, *Conducting Research on Sensitive Topics with Adolescents: Ethical and Developmental Considerations*, 26 J. OF DEV. & BEHAVIORAL PEDIATRICS 61 (2005).

⁵⁶ See Kopelman, *supra* note 6, at 752.

⁵⁷ See, e.g., *Grimes*, 782 A.2d at 846-850.

⁵⁸ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 26-28.

to identify and address the points relevant to research recruitment, decision making, and oversight, including investigator and IRB responsibilities.

A. RECRUITMENT PROCESS

Recruiting adolescents for research participation is challenging, because it raises a question of whether incentives should be used to facilitate this process. Incentives for research recruitment of adolescents are neither unethical nor illegal *per se*.⁵⁹ The federal regulations do not explicitly address payment or other incentives for research participation but direct that consent should be sought from research participants only under circumstances that minimize the possibility of coercion or undue influence.⁶⁰ Unable to demarcate a “bright line between proper and improper incentives” in interpreting this regulatory provision, other than to recommend that incentives be “age-appropriate,”⁶¹ the IOM has deferred to IRBs and institutions on the adoption of “written policies on the acceptability and the unacceptability of types or amounts of payment related to research participation.”⁶² In offering recommendations regarding payment incentives, the IOM recognizes the role that incentives play “in reducing barriers and equalizing access for participation.”⁶³

Yet, incentives for pediatric research remain a divisive issue. In particular, concerns persist about research propriety,

⁵⁹ *Id.* at 211-228.

⁶⁰ Protections for Children, *supra* note 11, at § 46.116 (a) & (b). *See also* THE BELMONT REPORT, *supra* note 20 (explaining that undue influence occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance). *Accord* 21 C.F.R. §§ 50.51-50.54, 56.03 (2003) (stating that recruitment of study participants should occur in a manner free from inappropriate inducement either to parents or legal guardians or the study participant).

⁶¹ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 227.

⁶² *Id.* at 224-225.

⁶³ *Id.* at 228.

especially misuse or abuse of minors, when compensation incentives are provided.⁶⁴ According to Maryland's highest court, material incentives to parents for enrolling children in non-therapeutic research are "inherently inappropriate" when such incentives entice parents to place their children in harm's way.⁶⁵ This 'inappropriateness' derives from two closely allied concerns: that financial incentives could distort parents' decision making about research participation, and that they could provide avenues for parents to promote self-interests and profit from exploiting children, who are unable to challenge their decision making.

The same concerns are not necessarily transferable to adolescents, however. Unlike children who are helpless and captive to parents' discretion or even desperation that influences a decision,⁶⁶ parents 'volunteering' adolescents seems unlikely. Involuntary or non-voluntary participation in research by adolescents is abated by their ability to resist authority,⁶⁷ in conjunction with their aversion to health-related activities.⁶⁸ Studies have shown that any susceptibility to parental influence and pressure is proportionate to the gravity of the decision. When the decisions involve matters of importance to adolescents and implicate their well-being, adolescents are likely to resist parental influence.⁶⁹ Additionally, adolescents' aversion

⁶⁴ *Id.* at 211-215; David G. Scherer et al., *Financial Compensation to Adolescents for Participation in Biomedical Research: Adolescent and Parent Perspectives in Seven Studies*, 146 J. PEDIATR. 552, 557 (2005).

⁶⁵ *Grimes*, 782 A.2d at 843-846.

⁶⁶ *See id.* at 852-856.

⁶⁷ *See* David G. Scherer & N. Dickon Reppucci, *Adolescents' Capacities to Provide Voluntary Informed Consent: The Effects of Parental Influence and Medical Dilemmas*, 12 LAW & HUM. BEHAV. 123, 132-136 (1988).

⁶⁸ Kenneth R. Ginsburg et al., *Adolescents' Perceptions of Factors Affecting Their Decisions to Seek Health Care*, 273 J. AM. MED. ASS'N 1913, 1917 (1995).

⁶⁹ Bruce Ambuel & Julian Rappaport, *Developmental Trends in Adolescents' Psychological and Legal Competence to Consent to Abortion*, 16 LAW & HUM. BEHAV. 129, 148-149 (1992); David G. Scherer, *The Capacities of Minors to Exercise Voluntariness in Medical Treatment Decisions*, 15 LAW & HUM. BEHAV. 431, 442-446 (1991); Scherer & Reppucci, *supra* note 67, at 132-136.

to health-related activities is attributable, in part, to their lack of incentive⁷⁰ that, although inconclusive, may have also contributed to their avoidance of research participation. Thus, payment incentives for adolescents may promote conscientious behavior, thereby increasing their enrollment in research participation arising out of a perception of both self-gain and a commitment to others.⁷¹

Moreover, other considerations argue for why remuneration may benefit adolescents beyond increasing their research participation. Although incentives may initially induce adolescents to participate, research participation has been shown to expose adolescents to virtues of selflessness and self-purpose comprising altruism. Through research participation, adolescents develop altruistic inclinations toward others that enrich their self-reflection and personal sense of responsibility.⁷² Adolescents' responsible and accountable actions through partnership and collaboration with others often transcend research involvement in ways that have proven transformative in terms of mature, selfless decision making.⁷³ Furthermore, adolescents' exposure to activities that potentially improve the lives of their peers tends to elevate their maturity levels.⁷⁴ Also of significance is the personal meaning derived from non-therapeutic research participation by adolescents who had suffered with childhood afflictions and are sensitized to relieving others' suffering.⁷⁵ Succinctly stated, the benefits to adolescents

⁷⁰ Sharon R. Beier et al., *The Potential Role of an Adult Mentor in Influencing High-Risk Behaviors in Adolescents*, 154 ARCHIVES OF PEDIATR. & ADOLESC. MED. 327, 329-330 (2000); Ginsburg et al., *supra* note 68, at 1917.

⁷¹ See Koren et al., *supra* note 49, at 147.

⁷² See HENRY K. BEECHER, RESEARCH AND THE INDIVIDUAL: HUMAN STUDIES 124-125 (1970).

⁷³ See ROOTS OF CIVIC IDENTITY: INTERNATIONAL PERSPECTIVES ON COMMUNITY SERVICE AND ACTIVISM IN YOUTH (Miranda Yates & James Youniss eds., 1999) (noting that the findings challenge the stereotypical shallow image of adolescents).

⁷⁴ Alfio Maggiolini et al., *Self-Image of Adolescent Survivors of Long-term Childhood Leukemia*, 22 J. PEDIATR. HEMATOL./ONCOL. 417, 419-420 (2000).

⁷⁵ *Id.*

from non-therapeutic research involvement are not inconsequential.

Structuring incentives responsive to adolescents is crucial to sustain their participation for the length of a study, especially in longitudinal studies that require ongoing involvement into and possibly throughout adulthood.⁷⁶ Compensation incentives, for example, could encourage participants' compliance with long-term studies. To this end, the IOM recommends that researchers explain to adolescents how withdrawing from a study would affect any payment that they would have received.⁷⁷ Maximizing adolescents' participation and retention suggests a correlation between the nature of the incentives and the research, inviting empirical inquiry.

Compensation incentives, therefore, should not be foreclosed to adolescent research participants solely on indeterminate grounds of coercion or undue influence. Failing to provide incentives could actually prove a disincentive to adolescents that is incompatible with the IOM's objectives. Self-purpose, along with a perception they are trusted and counted on, constitute countervailing benefits for adolescents that override marginal concerns about incentive offerings. Put differently, adolescents' perception that their participation is not only worthwhile but also trustworthy provides strong incentive that can translate into a sense of moral responsibility for research retention and compliance.

B. CONSENT PROCESS

Recruiting adolescents for research segues into the decision-making process. The process for deciding about whether to participate in a research study can benefit adolescents incalculably. It affords exposure to educational and collaborative experiences from which decision-making skills can be cultivated.⁷⁸ It also allows adolescents to perceive that they

⁷⁶ See Swallen et al., *supra* note 15, at 340.

⁷⁷ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 213-227.

⁷⁸ See Lois Weithorn & David G. Scherer, *Children's Involvement in Research Participation Decisions: Psychological Considerations*, in CHILDREN

are taken seriously and respected in ways that deepen developing self-image.⁷⁹ The IOM recognizes the importance of the consent process to adolescent decisional development and recommends research autonomy for mature minors.⁸⁰

The federal regulations require consent forms,⁸¹ which must not be elevated over substance when used in this decisional process. Despite regulatory requirements that consent forms must be both comprehensive and comprehensible,⁸² these forms have not insulated institutions and investigators from civil liability.⁸³ As several courts have emphasized, consent processes for research participation depend far more on the quality of information disclosure and the ensuing discussion than on standardized forms.⁸⁴ Thus, the consent process, as the *sine qua non* for ethically conducting non-therapeutic research with adolescent participants, compels careful scrutiny.

1. PARENT AUTHORITY AND WAIVER

The federal regulations require parental consent and the child's assent for non-therapeutic research participation, as previously mentioned.⁸⁵ The parental consent requirement is

AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW 152-156 (Michael Grodin & Leonard H. Glantz eds., 1994).

⁷⁹ Beier et al., *supra* note 70, at 329-330; Ginsburg et al., *supra* note 68, at 1917-1918.

⁸⁰ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 64-66, 181-186.

⁸¹ Protections for Children, *supra* note 11, at § 46.109.

⁸² *Id.* at § 46.117.

⁸³ *See, e.g., Grimes*, 782 A.2d at 807; *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

⁸⁴ *See Grimes*, 782 A.2d at 807; *Moore*, 793 P.2d at 479. *See also* COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 149-150 (emphasizing that forms are subordinate to the process for decision making).

⁸⁵ Protections for Children, *supra* note 11, at § 46.406 (d). *See also supra* notes 25-26 and accompanying text.

thought to shield vulnerable minors from research-related risks.⁸⁶ It also suggests a proxy decision-making model regarded as appropriate when research subjects are incompetent, but ethically and legally problematic when the prospective research subjects may be decisionally capable. If adolescents are proven capable to determine their participation in non-therapeutic research, the assent requirement is pernicious by minimizing the benefits adolescents could derive from autonomous decision making while also undermining the ethical principle of justice by constraining their unencumbered access to research involvement.⁸⁷ The dual consent requirement is premised on an assumption that adolescents lack the requisite capacity for autonomously deciding research participation, which is hindered by the paucity of evidence supporting it.

Moreover, assent—affirmative agreement to participate in research⁸⁸—is imprecise and, in practice, unstructured,⁸⁹ making it specious regarding children,⁹⁰ let alone adolescents for whom it is not easily operational.⁹¹ Disinterest and rebellion against parental consent are not altogether unpredictable; adolescents are more inclined to participate in research as a result of their own independent decision making.⁹² Prevailing studies with

⁸⁶ See Glantz, *supra* note 5, at 230-232.

⁸⁷ THE BELMONT REPORT, *supra* note 20, at 5; COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 9.

⁸⁸ Protections for Children, *supra* note 11, at § 46.402 (b).

⁸⁹ See Jennifer M. Cohn et al., *Adolescent Decisional Autonomy Regarding Participation in an Emergency Department Youth Violence Interview*, 5 AM. J. BIOETHICS 70, 72-73 (2005).

⁹⁰ Jennifer Rosato, *The Ethics of Clinical Trials: A Child's View*, 28 J.L. MED. & ETHICS 362, 366 (2000) (noting that “[e]ven the child’s veto power in the research consent is not necessarily binding”).

⁹¹ See generally Theresa O’Lonegan & John J. Zodrow, *Pediatric Assent: Subject Protection Issues Among Adolescent Females Enrolled in Research*, 34 J.L. MED. & ETHICS 451 (2006); Robert J. Levine, *Adolescents as Research Subjects without Permission of their Parents or Guardians: Ethical Considerations*, 17 J. ADOLESC. HEALTH 287 (1995).

⁹² See Cohn et al., *supra* note 89, at 72-73.

adolescents support this assertion, suggesting that parental presence inhibits and interferes with adolescents' willingness to engage openly and forthrightly with clinical investigators.⁹³ A reasonable inference is that adolescents will withhold intimate information and withdraw when they perceive that their parents disregard what they think or feel. Even if adolescents passively agree to research participation *vis-à-vis* parental consent, they are deprived the inestimable benefits of an autonomous decision-making process, including the confidence and poise resulting from one's own self-reflection and judgment.

Parents' axiomatic decisional authority is not unlimited over either children or adolescents; it is by no means absolute to the exclusion or subordination of all other interests, including that of their own children.⁹⁴ Courts routinely undertake hybrid due process and best interest analyses when parents seek sterilization of children,⁹⁵ or request skin for grafting⁹⁶ or a kidney for transplant from a child for a sibling.⁹⁷ Central to the courts' minor-centered analysis is the psychological benefit in proportion to risk exposure. Simply put, a limitation on parents' decision-making authority is risk exposure with little or no psychological benefit to the minor.

Given the psychological benefits derived from independent decision making about research participation, *a fortiori* disallowing adolescents' autonomy about their participation belies rather than bolsters ethical principles of beneficence, nonmaleficence, and justice. Denying adolescents decisional autonomy is deleterious to developing cognitive abilities by decreasing exposure to altruistic influences and unselfish

⁹³ Katia Geluda et al., *Third-Party Informed Consent in Research with Adolescents: The Good, The Bad, and the Ugly*, 61 SOCIAL SCIENCE & MED. 985, 986-988 (2005); Cohn et al., *supra* note 89, at 72-73; Caskey & Rosenthal, *supra* note 55, at 64-67; Melissa A. Meade & Natasha Slesnick, *Ethical Considerations for Research and Treatment with Runaway and Homeless Adolescents*, 136 J. PSYCHOL. 449, 451-458 (2002).

⁹⁴ *See, e.g.*, Prince v. Massachusetts, 321 U.S. 158, 166-170 (1944).

⁹⁵ *See, e.g.*, Matter of A.W., 637 P.2d 366 (Colo. 1981).

⁹⁶ *In re* Sidney Cowan, No. 180564 (Probate Ct. Jefferson Co., Ala. 2003).

⁹⁷ Hart v. Brown, 289 A.2d 386 (Conn. 1972).

service,⁹⁸ and by disadvantaging adolescents' evolving self-image. Studies of adolescents emphasize that engagement in decisional activities, especially engagement that enhances others' lives, provides adolescents with a sense of identity and accomplishment.⁹⁹

The federal regulations accord IRBs discretion for waiving parental consent insofar as the research relates to conditions or subject populations for which requiring parental consent seems unreasonable and the waiver would not be inconsistent with state law.¹⁰⁰ Should an IRB deem waiver appropriate, it must nonetheless determine a mechanism for protecting minors who participate as research subjects. The nature and purpose of the activities described in the protocol, the risks in relation to the benefits, and a composite of age, status, and condition inform an IRB's determination.¹⁰¹ Not enough is known, however, about the actual indicia that influence IRBs in making those determinations.¹⁰² Moreover, state law does not provide any additional guidance because statutes related to adolescents' research participation are essentially nonexistent. In this developing area, statutory silence suggests legislative inattention rather than intention to exclude adolescents from exercising legal autonomy. Accordingly, regulatory ambiguities should not be construed to hinder adolescent research involvement.

State statutes affording decisional autonomy for medical conditions such as STDs have been asserted as a basis for accepting consent from adolescents for involvement in research about related conditions.¹⁰³ However, state legislatures enacting

⁹⁸ See BEECHER, *supra* note 72, at 63-64.

⁹⁹ See ROOTS OF CIVIC IDENTITY, *supra* note 73. See also Beier et al., *supra* note 70, at 329-330 (finding that self-image is linked to positive contributions to the life, development, and behavior of other youth).

¹⁰⁰ Protections for Children, *supra* note 11, at § 46.408 (c).

¹⁰¹ *Id.* at § 46.408 (c).

¹⁰² See Rogers et al., *supra* note 41, at 7-10; Mammel & Kaplan, *supra* note 41, at 324-330.

¹⁰³ See Abigail English, *Guidelines for Adolescent Health Research: Legal Perspectives*, 17 J. ADOLESC. HEALTH 277 (1995).

adolescent medical decision-making statutes did not consider the complexities of research participation. For example, policy goals of preventing contagious disease and its progression underlying STD treatment statutes¹⁰⁴ are inapposite to the distinct policy concerns related to research participation. Furthermore, relying on statutes designed for adolescent consent to treatment rather than for research participation stultifies policy attention deserved by specific research-related issues. Statutes affording autonomy to adolescents for non-therapeutic research involvement should reflect studied consideration of these distinct issues.

Absent statutory enactment, interpretation and implementation of federal regulatory provisions, such as waiver of parental consent, should be construed in the broader context of adolescent decision-making abilities.¹⁰⁵ It is not clear whether determinations about parental waiver are reliably deferred to IRBs, given the void of information regarding the extent to which IRBs grant waiver or even consider it. However, it is clear that institutional misgivings exist about allowing adolescents to decide research participation without parental consent because of the dearth of statutory or common law explicitly authorizing it. This is complicated by a tendency for blind adherence to factual and theoretical assumptions about adolescents' capabilities that contravene developmental research. This research is relevant, precisely because the law has justified differential treatment of minors on developmental grounds. Reliance on crude assumptions about adolescents' decisional abilities are also contrary to state *parens patriae* for fostering adolescents' welfare. Government-engineered recognition of adolescents' capabilities through provisions affording them decisional autonomy for non-therapeutic research participation would better facilitate adolescents' welfare by enabling educational experiences and by encouraging unselfish service as

¹⁰⁴ Hartman, *supra* note 10, at 416.

¹⁰⁵ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 200-201.

they evolve into empowered autonomous individuals in society.¹⁰⁶

The IOM recommends using a 'mature minor' decision-making standard,¹⁰⁷ and thus particularized policy attention should focus on facilitating adolescent decisional autonomy rather than on waiving parent consent. It suggests developing policies predicated on adolescent decision making, though imperfections are inherent to any approach for maximizing participants' autonomy.¹⁰⁸ Short of affording adolescents complete decisional sovereignty, waiver of parental consent should be evaluated in relation to actual decisional abilities. Alternatively, adolescents could be presumed decisionally capable to consent for research participation. Under a presumptive decisional model, parental consent would be required only if the adolescent is assessed incapable for decision making based on factors such as age, experience, and risks involved in research participation.

An adolescent autonomy framework for non-therapeutic research participation should nonetheless integrate a mechanism for adult guidance. Intuitively, adolescent-initiated requests for parental input optimize that guidance. Surveys of adolescents suggest natural inclinations to seek out parents for advice on important matters.¹⁰⁹ In circumstances where parental guidance is neither forthcoming nor possible, other avenues for adult guidance should be incorporated so as to not

¹⁰⁶ See *Prince*, 321 U.S. at 168 (declaring that a "democratic society rests, for its continuance, upon the health, well-rounded growth of young people into full maturity as citizens, with all that implies").

¹⁰⁷ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 181-186.

¹⁰⁸ Amar D. Trivedi, *Rethinking Adolescent Assent: A Triangular Approach*, 5 AM. J. BIOETHICS 75, 75-76 (2005); Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 924-938 (1994). See also Henry K. Beecher, *Consent in Clinical Experimentation: Myth and Reality*, 195 J. AM. MED. ASS'N 34, 34 (1966) (explaining that "informed consent is often exceedingly difficult or impossible to obtain in any complete sense").

¹⁰⁹ See Beier et al., *supra* note 70, at 329-330 (stating that many adolescents turn to parents for advice); see also Ambuel & Rappaport, *supra* note 69, at 150-151 (noting that many minors seek parental input before making decisions).

deter or dissuade adolescents from research participation.¹¹⁰ This is especially true for runaway or homeless adolescents whose inclusion may prove invaluable for both the adolescent and the investigator.¹¹¹ Parental consent could be required only in those situations where reducing research-related injuries is an overriding interest due to the magnitude and probability of risk exposure.¹¹²

2. ADOLESCENT DECISIONAL AUTONOMY

Adolescents constitute a conundrum for law and policy, primarily because the law continues to reflect the conventional norm that adolescents lack capabilities for legal autonomy.¹¹³ Current regulations governing minors' participation in clinical trials do not recognize adequately adolescents' decisional capabilities that compare to young adults in varied contexts.¹¹⁴ Because research participation enhances self-esteem that can decrease vulnerability thought to impair responsible judgment,¹¹⁵ legal policy that fails to recognize decisional autonomy undermines ethical principles for promoting adolescents' best interests and preventing harm. Specifically,

¹¹⁰ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 186 (concluding that the decisional capacity of adolescents merits consideration).

¹¹¹ Meade & Slesnick, *supra* note 93, at 455-457.

¹¹² See *generally* COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 181-186.

¹¹³ See *generally* Rhonda Gay Hartman, *Adolescent Autonomy: Clarifying an Ageless Conundrum*, 51 HASTINGS L. J. 1265 (2000).

¹¹⁴ See, e.g., Ambuel & Rappaport, *supra* note 69, at 148-151 (arguing that bright line legal mechanisms are ineffective measures of competence); Catherine C. Lewis, *A Comparison of Minors' and Adults' Pregnancy Decisions*, 50 AM. J. ORTHOPSYCHIATRY 446, 451 (1980) (reporting no discernible differences between minors and adults "in their knowledge of the legality and confidentiality of abortion" or in their decision making).

¹¹⁵ See, e.g., Lena A. Sancu et al., *Youth Related Research Ethics: Time for a Mature-Minor Clause?*, 180 MED. J. AUSTL. 336, 337-338 (2004) (arguing that exclusion from research participation undermines adolescents' autonomy).

adolescents tend to become disillusioned and disengaged when they perceive they are treated condescendingly and not taken seriously.¹¹⁶

The IOM report encourages eliciting consent from mature minors.¹¹⁷ Adolescents' mature judgment for research involvement has been reported,¹¹⁸ reinforcing other evidence suggesting decisional capacities comparable to that of young adults in clinical contexts.¹¹⁹ If, as this evidence reveals, adolescents are capable to decide participation in clinical trials, then denying them autonomy unnecessarily precludes research inclusion along with the substantial benefits that might be gained from both the research and adolescents' participation in it.¹²⁰ Unless other theoretical or factual bases exist to deny adolescents decisional autonomy for research participation, the argument that adolescents' decisional liberty rights are impermissibly infringed is tenable.¹²¹ Findings from studies of adolescents' capabilities suggest their abilities to volunteer for non-therapeutic research participation and understand both the risks and the volitional nature of their involvement.¹²² However,

¹¹⁶ See, e.g., Kenneth R. Ginsburg et al., *Factors Affecting the Decision to Seek Health Care: The Voice of Adolescents*, 100 PEDIATRICS 922, 925 (1997) (finding that adolescents sought respect from practitioners and resented feeling belittled).

¹¹⁷ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 186.

¹¹⁸ Cohn et al., *supra* note 89, at 72-73.

¹¹⁹ See, e.g., Ambuel & Rappaport, *supra* note 69, at 147-148 (finding no significant difference in the competence or volition of adolescents and young adults); see also Lewis, *supra* note 114, at 451.

¹²⁰ See THE BELMONT REPORT, *supra* note 20, at 4 (ethical principles demand respect for the autonomy of competent persons).

¹²¹ See Hartman, *supra* note 13, at 299-305 (criticizing judicial justifications for the continued restriction of adolescent consent).

¹²² See, e.g., Cohn et al., *supra* note 89, at 72-74 (concluding that adolescents possess decisional capacity even in emotionally difficult situations); see also Geluda et al., *supra* note 93, at 986-987 (advocating change in consent requirements for adolescent participation in opinion and perception research).

those findings signal the need for scientific and social-scientific study that focuses on identifying and refining variables suitable for adolescent capacity measurement prior to drawing definitive conclusions.¹²³

Should research indicate there are no scientifically measurable differences between adolescents and young adults in the nature and degree of decisional ability about non-therapeutic research participation, the idea that adolescents should not be precluded from research decision making becomes manifest and further erodes the legal supposition that adolescents are incapable of decision making. This supposition may be traced to the Supreme Court's invocation of it in 1979.¹²⁴ In order to uphold parental consent restrictions on adolescents' abortions, the Court cited 'conventional' assumptions about immaturity, vulnerability, and adult guidance.¹²⁵

Although extending decisional liberty to adolescents, the Court legitimized the restrictions by focusing on adolescents' "peculiar vulnerability".¹²⁶ However, the Court did not develop how vulnerability should be judged, especially in non-abortion contexts, in order to justify constraints on adolescents' decisional liberty. Rather than evaluating adolescent vulnerability in particular contexts, lower courts and legislatures have simply subscribed to presumptive decisional inability, unless countervailing evidence of maturity is adduced.¹²⁷ Consequently, parental notification and consent are routinely required, subject only to evidence in a specific case that refutes the presumption or a statutory exception that affords decisional autonomy to adolescents.

¹²³ See Rhonda Gay Hartman, *Adolescent Decisional Autonomy for Medical Care: Physician Perceptions and Practices*, 8 U. CHI. L. SCH. ROUNDTABLE 87, 123-124 (2001) (proposing goals for future research).

¹²⁴ *Bellotti v. Baird*, 443 U.S. 622, 634 (1979).

¹²⁵ *Id.* at 634.

¹²⁶ *Id.* at 635-36.

¹²⁷ See, e.g., *In re Application of Long Island Jewish Med. Ctr.*, 557 N.Y.S.2d 239, 242-43 (N.Y. Sup. Ct. 1990) (holding that an adolescent patient was not legally competent to make a medical decision).

Then, as now, evolving empirical evidence about adolescents' abilities contradicts the Court's assumptions, collapsing the presumptive incapacity supposition. Studies suggest that adolescents' vulnerability, or susceptibility to external influences, typically does not exceed that of young adults.¹²⁸ They also indicate that, although amenable to parents' insights, adolescents resist undue influence or coercion when deciding important matters,¹²⁹ thereby weakening the Supreme Court's sweeping assertion that adolescents lack capacity "for making life's difficult decisions."¹³⁰ Nor are adolescents necessarily more risk-prone in decision making.¹³¹ Other evidence substantiates indistinguishable differences in decision-making capabilities between adolescents and young adults in stressful contexts.¹³² Accordingly, the evidence suggests that adolescents are not vulnerable *per se*. Rather, for adolescents, like adults, vulnerability depends on the situation.

In light of existing empirical evidence, restrictions on adolescent decision making about research participation seem to be hoisted on a petard of their own design. Consequently the restrictions excluding adolescents from participating in non-therapeutic research that may have long-term consequences for their well-being are indefensible both factually and ethically. This evidence signals the need for a paradigmatic shift to a consent process for adolescent participation in non-therapeutic

¹²⁸ See, e.g., Marilyn Jacobs Quadrel et al., *Adolescent (In)Vulnerability*, 48 AM. PSYCHOLOGIST 102, 111-112 (1993) (finding that adults and adolescents rely on similar processes in evaluating vulnerability to risk).

¹²⁹ Ambuel & Rappaport, *supra* note 69, at 148; see also Scherer & Reppucci, *supra* note 67, at 132-136 (observing that, in serious situations, adolescents proved more resistant to excessive parental pressure).

¹³⁰ *Parham v. J.R.*, 442 U.S. 584, 602 (1979).

¹³¹ See, e.g., Rita Shapiro et al., *Risk-Taking Patterns of Female Adolescents: What They Do and Why*, 21 J. ADOLESCENCE 143, 157 (1998) (reporting that college-aged students took more risks than younger adolescents); see also Quadrel et al., *supra* note 128, at 114 (finding that relative exposure to risk by adults and adolescents is unclear).

¹³² See, e.g., Ambuel & Rappaport, *supra* note 69, at 147-48 (finding no significant difference in the competence or volition of adolescents and young adults); Lewis, *supra* note 114, at 451.

research that is structured on their decisional capabilities, though more empirical study is required. In other words, a sensible approach would be to afford adolescents decision-making autonomy and either require a parent's assent to ensure inclusion of adult guidance, or conversely, researchers should encourage adolescents to consult with a parent, to whom adolescents tend to turn in their decisional process.¹³³ Insofar as the ethical principles of respecting persons and promoting participants' interests are prioritized when conducting research,¹³⁴ justice demands that adolescents should not be denied opportunities for personal development and educational enrichment through autonomous decision making about participating in non-therapeutic research.

It has been contended that parental consent and adolescent assent occur in tandem as a result of a joint conversation with the investigator.¹³⁵ Under this approach, the adolescent would be afforded a chance to articulate his or her views about research participation to both the investigator and parent, along with being privy to their discussion.¹³⁶ In spite of the opportunity for adolescents to express their views in parents' presences that reciprocally afford parental consideration of adolescents' comments,¹³⁷ this approach would essentially sustain the *status quo* that does little to advance the IOM's aims for increasing adolescent participation.

Specifically, it is shortsighted to assume that a parent's presence and contributions to the conversation would assuage an adolescent's anxieties and richen consideration about research involvement. Scientific and social-scientific study repudiate this assumption, revealing that parental presence in

¹³³ See generally Beier et al., *supra* note 70; see also Ambuel & Rappaport, *supra* note 69, at 150 (suggesting that a legal presumption of competence may be justified by both actual capacity and adolescents' tendency to seek adult guidance).

¹³⁴ THE BELMONT REPORT, *supra* note 20, at 4-5.

¹³⁵ Trivedi, *supra* note 108.

¹³⁶ *Id.* at 75-76.

¹³⁷ *Id.*

decision making about research involvement poses difficulties by causing adolescents, who might otherwise connect and converse with investigators, to become reticent and ultimately disengage. Such concerns are not only counterproductive to the IOM's aims but also to the ethical pillars on which human subject research is justified.¹³⁸

Other studies with adolescents underscore those concerns, indicating that a parent's presence inhibits and interferes with an adolescent's desirability to engage openly and forthrightly with clinical investigators.¹³⁹ One explanation may be that the parental presence increases the potential that the adolescent's views may be marginalized and disregarded by the parent in the investigator's presence, causing an adolescent to withdraw from the conversation and, at most, passively agree. A related reason is that parental authority may intensify the sense that the adolescent's views neither matter nor are respected,¹⁴⁰ which can blunt developmental abilities derived distinctly from independent decision making about research activities. This three-way conversational dynamic presaging the parent's decision could likely create, rather than alleviate, a setting conducive to subtle coercions,¹⁴¹ in contradistinction to ethical principles for maximizing benefits, minimizing harms, and promoting research involvement that is undertaken by the participant freely and voluntarily.¹⁴² More critically, it could impede researchers' chances to connect with adolescents in

¹³⁸ See generally THE BELMONT REPORT, *supra* note 20.

¹³⁹ See Wilma C. Rossi et al., *Child Assent and Parental Permission in Pediatric Research*, 24 THEORETICAL MED. & BIOETHICS 131, 141-142 (2003) (citing several subtle factors of parental influence on adolescents' decisions).

¹⁴⁰ Ginsburg et al., *supra* note 116, at 925 (finding that adolescents view disclosure to their parents, despite promises of privacy, as a sign of disrespect).

¹⁴¹ See Rossi et al., *supra* note 139, at 141-142.

¹⁴² See generally THE BELMONT REPORT, *supra* note 20; see also Sancu et al., *supra* note 115, at 336-338 (noting that parental consent requirements hinder adolescent participation in beneficial research).

order to educate and to intervene in behaviors that are deleterious to an adolescent's health and well-being.¹⁴³

Additionally, adolescents tend to derive a sense of confidence and self-control from believing that their privacy is maintained. Privacy assurances provide an impetus for articulating their views candidly.¹⁴⁴ It seems improbable, based on the current empirical evidence, that adolescents will disclose sensitive personal information during that 'triangular' conversation that may prove crucial to the nature of the research itself as well as to their participation. The positive aspects that result from a three-way conversation would be better achieved by affording adolescents decisional autonomy about non-therapeutic research participation and by obviating potential obstacles that may weaken, rather than strengthen, the IOM's objectives for increasing research participation. And, as mentioned earlier, adolescents have been shown to consult with a parent when confronting decision making about matters of significance to them.¹⁴⁵ Therefore, a conversation with a parent about participation in non-therapeutic research may ultimately prove more meaningful when the adolescent initiates the dialogue following an initial meeting with investigators who encourage and support the adolescent's consultation with a parent.

¹⁴³ See, e.g., Eric T. Moolchan & Robin Mermelstein, *Research in Tobacco Among Teenagers: Ethical Challenges*, 30 J. ADOLESC. HEALTH 409, 412-413 (2002) (finding that adolescents may not participate in tobacco-use research if parental consent is needed); see also Meade & Slesnick, *supra* note 93, at 452-463 (arguing that parental consent requirements have a deleterious effect on the ability of runaway adolescents to benefit from treatment).

¹⁴⁴ See, e.g., Carol A. Ford et al., *Influence of Physician Confidentiality Assurances on Adolescents' Willingness to Disclose Information and Seek Future Health Care*, 278 J. AM. MED. ASS'N 1029, 1033-1034 (1997) (commenting that lack of privacy can injure communication between adolescents and physicians); Ginsburg et al., *supra* note 116, at 927-928 (reporting adolescents' concern for confidentiality with regard to parents, medical staff, and the public). See *infra* notes 146-160 and accompanying text.

¹⁴⁵ See *supra* note 109 and accompanying text.

C. PRIVACY PROTECTIONS

Privacy protections may prove to be a singularly powerful incentive for increasing adolescent research participation. Confidentiality is central to any decision-making process; adolescents, like adults, derive dignity from knowing that their confidences are maintained.¹⁴⁶ Adolescents ascribe importance to confidentiality, which has been shown to influence their willingness to access basic health care, communicate with providers, and return for follow-up visits.¹⁴⁷ It also influences their willingness to participate in research.¹⁴⁸ Thus, privacy protections for adolescents participating in non-therapeutic research must not be underestimated and could prove pivotal to achieving the IOM's aims for increasing their research involvement and retention. Scientific and social-scientific studies reinforce this point; without privacy assurances adolescents are less inclined to confide and more inclined to self-censure.¹⁴⁹

Confidentiality's vitality in adolescent decision making is clear. Less clear is how it should be extended to adolescents who participate in non-therapeutic research. The federal regulations are silent as to confidentiality safeguards. Privacy protections for adolescents participating in research are also notably absent in state statutory law, on which federal regulations rely.¹⁵⁰ The IOM's report, moreover, does not squarely address adolescent privacy or recommend how confidentiality protections could be implemented for adolescents. If the IOM's aims for increasing adolescent

¹⁴⁶ See Hartman, *supra* note 123, at 112-113 (discussing confidentiality as the foundation for the relationship between medical practitioners and adolescent patients); see also Ford et al., *supra* note 144, at 1033-1034 (finding that confidentiality concerns were crucial to adolescents' decisions to seek health care).

¹⁴⁷ Ginsburg et al., *supra* note 68, at 1917.

¹⁴⁸ See Cohn et al., *supra* note 89, at 72-73.

¹⁴⁹ See, e.g., Ford et al., *supra* note 144, at 1029; Ginsburg et al., *supra* note 116, at 922.

¹⁵⁰ Protections for Children, *supra* note 11, at § 46.402 (a).

research participation are to be achieved, then attention focused on explicit confidentiality assurances is crucial. Privacy protections are essential to any approach for increasing adolescent research participation.

More to the point, confidentiality assurances reduce adolescents' inhibitions to connect and communicate with investigators, especially in stressful settings.¹⁵¹ Published findings demonstrate adolescents' concerns about confidentiality that dramatically influence their willingness to confide in health care professionals.¹⁵² For example, health care providers' assurances to adolescents that confidentially will be maintained increase not just their willingness to initially access care but also to return for additional care.¹⁵³

Those findings strengthen the need for investigators to assure adolescents that their privacy will be safeguarded during both the recruitment and consent processes, thereby engendering a perception of mutual respect and reliance that enhances adolescents' receptiveness. Yet additional research is needed to determine how investigators can effectively convey confidentiality assurances and what the most conducive conditions are for doing so. This is particularly critical when the research focuses on sensitive matters such as substance use,¹⁵⁴ sexual activity and abuse,¹⁵⁵ and homelessness.¹⁵⁶

Beyond empirical and scientific findings that underscore privacy's importance in interactions with adolescents, courts

¹⁵¹ See Cohn, et al., *supra* note 89, at 72-73.

¹⁵² See Ford et al., *supra* note 144, at 1033-1034.

¹⁵³ *Id.*

¹⁵⁴ See Caskey & Rosenthal, *supra* note 55, at 63-67; Gill Highet, *Cannabis and Smoking Research: Interviewing Young People in Self-Selected Friendship Pairs*, 18 HEALTH EDUCATION RESEARCH 108, 112-117 (2003); Moolchan & Mermelstein, *supra* note 143, at 411-417.

¹⁵⁵ Karin Helweg-Larsen & Helmer Boving-Larsen, *Ethical Issues in Youth Surveys: Potentials for Conducting a National Questionnaire Study on Adolescent Schoolchildren's Sexual Experiences with Adults*, 93 AM. J. PUBLIC HEALTH 1878, 1879-1882 (2003).

¹⁵⁶ Meade & Slesnick, *supra* note 93, at 451-458.

trend toward an adolescent-centered approach for protecting confidential communications.¹⁵⁷ Illustrative are appellate court rulings that parental interests cede to adolescent privacy interests in conflicts over disclosure of confidential information.¹⁵⁸ A Florida appellate court, for instance, ruled that an adolescent, rather than her parents, was entitled to assert the statutory privilege of confidentiality in a case involving the parents' request for disclosure of information that the adolescent had shared with a therapist. In so ruling, the court distinguished the decisional capabilities of adolescents apart from minors younger than fourteen years, recognizing privacy's significance to adolescents' cognitive development. Additionally, the court referenced the evolving statutory law that increasingly affords adolescents decisional autonomy in medical and mental health care, custody disputes, and criminal matters, and delegated to the state legislature the task to "review the substantial policy issues" attendant to adolescent confidentiality.¹⁵⁹ Several states, such as Massachusetts, protect adolescents' confidentiality concerning their medical information through statutory provisions.¹⁶⁰

Common law and statutory trends, coupled with scientific findings, imply that adolescents' unwanted disclosure of information could deter them from conversing with investigators and committing to participating throughout the length of a study. Mere perception of unwanted information disclosure could dissuade adolescents from research participation altogether. The nature of the research, moreover, may necessitate confidential counseling,¹⁶¹ in addition to interactions with clinical investigators.

¹⁵⁷ See, e.g., *Attorney Ad Litem for D.K. v. Parents of D.K.*, 780 So.2d 301 (Fla. Dist. Ct. App. 2001).

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*; see also *Doe v. High Tech Inst., Inc.*, 972 P.2d 1060 (Colo. Ct. App. 1998) (extending legal protections to adolescent decision making about seclusion of information).

¹⁶⁰ MASS. GEN. LAWS ANN. ch. 112, § 12F (West 2005).

¹⁶¹ See Helweg-Larsen & Boving-Larsen, *supra* note 155, at 1879-1880.

The federal regulations governing research with minors should be revised to explicitly protect adolescents' confidential communications. Short of regulatory revision, state statutes—on which federal regulations rely—should be enacted to safeguard adolescent communications related to non-therapeutic research participation. Alternatively, state policymakers could devise legislation that presumptively protects adolescent privacy in health and biomedical research generally, placing on the party seeking disclosure the burden of adducing evidence that such disclosure is necessary to prevent substantial endangerment or harm to the adolescent. To this end, more empirical investigation is needed to inform policymakers about confidentiality's impact on adolescent decision making for non-therapeutic research participation.¹⁶²

D. RESEARCHERS' ROLES AND RESPONSIBILITIES

The relationship between researchers and subjects, though ill defined in law and policy, is “unique”¹⁶³ and distinguishable from a physician's role to a patient because it is driven by knowledge advancement and acquisition.¹⁶⁴ Despite both the prevalence and significance of human subject research, there is comparatively little statutory or case law that defines researchers' roles and responsibilities to participants, especially when injuries or other harms occur. The few courts addressing the investigator-subject relationship have applied negligence and fiduciary obligation theories arising from the doctor-patient relationship.¹⁶⁵ Those theories involve duties of care and loyalty owed to patients when physicians' personal or professional interests potentially compromise their judgment.¹⁶⁶

¹⁶² See *infra* notes 219-220 and accompanying text.

¹⁶³ See *Grimes*, 782 A.2d at 838.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at 841-846; see also *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

¹⁶⁶ *Moore*, 793 P.2d 479.

Yet it is not clear whether these duties should apply to clinical investigators when the research presents no prospect of medical benefit to the participant but, as in the case of adolescents, pose other tangible and intangible benefits.¹⁶⁷ Because fiduciary duties typically arise when one places trust in another who accepts that trust,¹⁶⁸ extending fiduciary obligations to those conducting research with adolescents is not wholly implausible. However, the clinical investigator does not commit to promote the research subjects' best interests. Rather, his first duty is to conduct the research properly, which suggests that applying a fiduciary duty to clinical investigators may be misguided.¹⁶⁹

Nonfeasance, or an obligation to prevent harm or endangerment to someone over whom power is wielded,¹⁷⁰ may be more appropriate for analyzing researchers' responsibilities to adolescent participants. This tort theory arises from a relation between the parties, one of whom is typically in some respect vulnerable and dependent on the other who, correspondingly, holds power over the other's welfare. The resulting power imbalance and relationship of trust are of such a character that social policy and laws justify the imposition of a duty to act.¹⁷¹ While nonfeasance is a legal theory, it also engenders ethical principles of beneficence and nonmaleficence that undergird federal regulations governing human subject experimentation.¹⁷² As applied to non-therapeutic research, a process should be devised whereby clinical investigators proceed responsively to maximize adolescents' safety and also consider

¹⁶⁷ See *supra* notes 72-75 and accompanying text.

¹⁶⁸ See *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F.Supp.2d 1043, 1064 (S.D. Fla. 2003).

¹⁶⁹ See generally E. Haavi Morreim, *The Clinical Investigator as Fiduciary: Discarding a Misguided Idea*, 33 J.L. MED. & ETHICS 586 (2005).

¹⁷⁰ W. PAGE KEETON ET AL., *PROSSER AND KEETON ON THE LAW OF TORTS* 373-374 (5th ed. 1984).

¹⁷¹ *Id.*

¹⁷² THE BELMONT REPORT, *supra* note 20, at 4-5.

avenues for forthright communication, education, and counseling.¹⁷³

Although the federal regulations do not delineate the roles and responsibilities of investigators conducting research with adolescents, the IOM has set forth several recommendations to this end. Specifically, it emphasizes an educational component for investigators to conduct research ethically,¹⁷⁴ and to ensure adolescents' safety by disclosing to them what may be expected throughout the course of a study.¹⁷⁵ Other than communicating in "developmentally appropriate ways" with pediatric subjects that include parental guidance,¹⁷⁶ the IOM does not elaborate on how education related to research participation or interaction between researchers and adolescent participants should unfold.

Investigators' roles and responsibilities are inestimable when conducting research with adolescents and command close scrutiny apart from research with children. Because adolescents rank clinicians low on their list of trusted adults,¹⁷⁷ clinical investigators are challenged to facilitate settings conducive to adolescent involvement and retention. Relaxed research environments could effectively increase adolescents' interest and improve the quality of insight they share with investigators about matters affecting their lives.¹⁷⁸

Mentorship, for instance, is not insignificant to increasing adolescent amenability for research participation. Mentorship plays a vital role in the lives of adolescents. It contributes dramatically to their development and decreases harmful

¹⁷³ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 250.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 248.

¹⁷⁶ *Id.* at 249-250.

¹⁷⁷ See Beier et al., *supra* note 70, at 329.

¹⁷⁸ See Janet L. Brody et al., *Family and Physician Influence on Asthma Research Participation Decisions for Adolescents: The Effects of Adolescent Gender and Research Risk*, 118 PEDIATRICS 356 (2006); Hight, *supra* note 154, at 108; J. Gans & C. Brindis, *Choice of Research Settings in Understanding Adolescent Health Problems*, 17 J. ADOLESC. HEALTH 306 (1995).

behaviors.¹⁷⁹ The importance placed by adolescents on a mentor stems from a perception that they learn from someone who cares and is more knowledgeable.¹⁸⁰ This, in turn, facilitates channels for confidential communication essential to adolescents' non-therapeutic research participation. Confidence and trust in those conducting the research can translate into adolescents' willingness to enroll and commit to ongoing research participation.¹⁸¹ How a mentorship model can be shaped for those conducting research with adolescents warrants closer scrutiny.

Moreover, adolescent decisional autonomy for non-therapeutic research participation should include adult guidance in order to enhance the developmental and educational benefits for adolescents as envisioned by the IOM.¹⁸² Investigators' accessibility for adolescents' questions and concerns throughout the study is critical for maximizing benefits that adolescents may derive from their research participation. Investigators conducting research with adolescents *a priori* should be vigilant in their approaches, including their style, and create settings for conveying information that are conducive to both increasing and retaining adolescents' participation.¹⁸³ Of some significance is investigators' sensitivity to communicating with adolescents¹⁸⁴ that is buttressed by studies indicating language usage is integral to adolescents' interrelationship with and

¹⁷⁹ See Beier et al., *supra* note 70, at 328, 330-331.

¹⁸⁰ *Id.* at 327, 330.

¹⁸¹ See, e.g., Cohn et al., *supra* note 89, at 72-73; Ginsburg et al., *supra* note 68, at 1917-1918. See also Scherer et al., *supra* note 64, at 556 (reporting that "adolescent research participants [in an HIV study] revealed that financial compensation was a relatively minor factor in their decisions to participate in research, compared with the importance of their relationship with research personnel").

¹⁸² COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 200-201.

¹⁸³ THE BELMONT REPORT, *supra* note 20, at 6 (recognizing that the process for information disclosure "can be as important as the information itself").

¹⁸⁴ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 198-199.

responsiveness to adults.¹⁸⁵ Ultimately, investigators' roles should develop commensurate with a mentorship model, thereby furthering the IOM's aims as well as regulatory policy goals for advancing both knowledge acquisition and adolescents' interests. This would also foster the ethical conduct of research by those who are savvy, conscientious, and compassionate with adolescent participants.¹⁸⁶

E. OVERSIGHT REVIEW PROCESS

Oversight of the ethical conduct of research with children rests primarily with IRB review.¹⁸⁷ The federal regulations assign to IRB review common sense estimates based on experience, available statistical information, and the subject's situation.¹⁸⁸ Underlying IRB review is the central "idea of systemic, nonarbitrary analysis of risks and benefits" rendering research assessment "rigorous and precise."¹⁸⁹ While the idea is laudable, implementation through IRBs has proven illusory.

Scrutiny of IRBs reveals systemic shortcomings, such as inadequacies of expertise and self-assessment, prompting proposals for reform.¹⁹⁰ These shortcomings contravene the idea behind IRBs, namely thorough accumulation and evaluation of information about all aspects of human subject experimentation.¹⁹¹ They also reduce the likelihood that

¹⁸⁵ See Ginsburg et al., *supra* note 68, at 1917.

¹⁸⁶ See Beecher, *supra* note 3, at 1360. Accord Edmund D. Pellegrino, *Character and the Ethical Conduct of Research*, 2 ACCOUNTABILITY IN RESEARCH 1 (1992).

¹⁸⁷ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 251.

¹⁸⁸ See Protections for Children, *supra* note 11, at §§ 46.107-46.111.

¹⁸⁹ See THE BELMONT REPORT, *supra* note 20, at 6.

¹⁹⁰ See, e.g., OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM (June 1998). Accord Michaele C. Christian et al., *A Central Institutional Review Board for Multi-Institutional Trials*, 346 NEW ENG. J. MED. 1405 (2002).

¹⁹¹ THE BELMONT REPORT, *supra* note 20, at 7.

research participants' rights, interests, and safety will be protected.¹⁹² According to a state high court, IRB oversight of clinical research with children is especially suspect because a review process designed for adult subject experimentation obscures issues specific to child or adolescent subjects.¹⁹³

Shortcomings notwithstanding, the IOM entrusts IRBs with the vital tasks of strengthening educational means and ensuring safeguards in the consent process, in addition to approving research protocols contingent on compliance with the risk and consent provisions.¹⁹⁴ The federal regulations outline IRB composition and responsibilities,¹⁹⁵ though the IOM emphasizes that requisite expertise among those appointed to serve on IRBs is essential.¹⁹⁶ IRB responsibilities in reviewing protocols must satisfy the regulatory requirements governing research with minors generally, including risk determinants for both therapeutic and non-therapeutic research.¹⁹⁷

Additional oversight by a panel convened by DHHS is required when risk-laden research would nevertheless further understanding, prevention, or alleviation of serious problems afflicting minors' health or welfare that includes determining whether the proposed research complies with other regulatory provisions or ethical measures for soliciting consent.¹⁹⁸ Yet, scrutiny of those special panels reveals substantial problems concerning compliance with consent provisions, incentive

¹⁹² See Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271 (addressing whether the federal regulations establishing the IRB system of oversight constitutes a "new kind of censorship" in violation of the First Amendment).

¹⁹³ *Grimes*, 782 A.2d at 846-848.

¹⁹⁴ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 251.

¹⁹⁵ Protections for Children, *supra* note 11, at §§46.107-46.111.

¹⁹⁶ COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 222-223, 251. *Accord* Rosato, *supra* note 90, at 372.

¹⁹⁷ Protections for Children, *supra* note 11, at §§ 46.107-46.111.

¹⁹⁸ Protections for Children, *supra* note 11, at § 46.407 (b) (1) & (2)(i)-(iii).

offerings, and injury compensation plans that have been neither resolved nor addressed, at least adequately.¹⁹⁹

IRB effectiveness in overseeing research that is conducted with adolescents could be improved by evaluating protocols within the context of global findings. Collaboration with other countries is crucial for acquiring comprehensive data specific to adolescents, but also for understanding about ongoing trials internationally and research that should be conducted.²⁰⁰ Global dissemination of information through international collaboration and the World Health Organization about ongoing and completed clinical trials with adolescent participants should be prioritized. An international registry of findings from research with adolescents should be maintained and consulted by IRBs (and investigators) when determining research protocols' contribution to scientific knowledge about improving adolescents' health and welfare.²⁰¹ International norms and standards are also desirable²⁰² because human values of dignity and decency transcend parochial interests when adolescents, or any persons, are used to generate knowledge geared primarily to benefit others.

The foregoing discussion has set forth the issues germane to legal policy analysis regarding adolescent participation in non-therapeutic research. The following section frames inquiries for empirical examination in order to develop a cohesive legal scheme that advances the IOM's aims.

¹⁹⁹ See Lainie Friedman Ross, *Lessons to be Learned from the 407 Process*, 15 HEALTH MATRIX 401, 417-420 (2005).

²⁰⁰ See Fiona Godlee, *International Standard for Disclosure of Clinical Trial Information*, 332 BRIT. MED. J. 1107 (2006).

²⁰¹ See COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 273 (urging creation of a centralized national registry of research trials involving minors).

²⁰² For a discussion of the United Nations Educational, Scientific, and Cultural Organization's adoption of the Universal Declaration on Bioethics and Human Rights and its salience as an international expression of norms for the development and application of biomedical science, see Anna Gercas, *Note, The Universal Declaration on Bioethics and Human Rights: Promoting International Discussion on the Morality of Non-Therapeutic Research on Children*, 27 MICH. J. INT'L L. 629 (2006).

IV. EMPIRICAL ISSUES AND IMPLICATIONS FOR LEGAL POLICY ANALYSIS

By identifying the issues central to adolescent participation in non-therapeutic research, the preceding discussion sets the stage for how scientific and social-scientific study can inform legal policy analysis. The law has been criticized as “policy analysis without benefit of data,”²⁰³ because legal rules routinely result from assumptions, guesswork, and “rigorless examination.”²⁰⁴ Quantitative and empirical social and behavioral sciences constitute the bellwether for directing regulatory reform to advance the IOM’s aims of increasing adolescent research involvement and state statutory enactment to supplement the existing federal regulations toward this end.

Data gathered from testing relevant policy questions through scientific and social-scientific investigation enriches policy development by providing a factual basis for regulatory revision or statutory enactment. Collaboration between social scientists and legal scholars on policy issues is requisite for advancing the “long and esteemed support for the idea of empirically evaluating legal policy.”²⁰⁵ Specifically, evidence gleaned from scientific and social-scientific investigation of the issues attendant to increasing adolescent research involvement essentially documents the effects of different approaches and enhances debate about the values that might promote a particular policy approach.²⁰⁶

²⁰³ Michael J. Saks, *Legal Policy Analysis and Evaluation*, 44 AM. PSYCHOLOGIST 1110, 1110 (1989).

²⁰⁴ *Id.* at 1111. See RICHARD LEMPERT & JOSEPH SANDERS, AN INVITATION TO LAW AND SOCIAL SCIENCE: DESERT, DISPUTES, AND DISTRIBUTION 12 (1986) (advocating a reciprocal relationship between lawmaking and socio-economic theory).

²⁰⁵ Legal realists, such as Karl Llewellyn, wrote about policy assessment research and “the conception of law as a means to social ends and not as an end in itself; so that any part needs constantly to be examined for its purpose, and for its effect, and to be judged in the light of both and of their relation to each other.” Karl Llewellyn, *Some Realism About Realism*, 44 HARV. L. REV. 1222, 1236 (1931).

²⁰⁶ Preston A. Britner et al., *Evaluating Juveniles’ Competence to Make Abortion Decisions: How Social Science Can Inform the Law*, 5 U. CHI. L. SCH.

A. ISSUES MERITING EMPIRICAL INVESTIGATION

The issues related to recruitment of adolescents for research participation are paramount to achieving the IOM's objectives. Information about enrollment settings and cultural/social norms that influence adolescent involvement in research is needed to design research participation that optimizes adolescents' perceptions of inclusion and involvement.²⁰⁷ The partnering of adolescents with peers, for example, has been shown to instill confidence and increase cooperation.²⁰⁸ In contrast, adolescents are less cooperative when family members are present.²⁰⁹ Additionally, empirical data is required for determining whether material incentives increase that involvement and, if so, whether incentives should include remuneration. Payment could prove a positive incentive for adolescents by inculcating a value of commitment and inspiring responsibility toward others who rely upon them.²¹⁰ A related inquiry concerns a correlation between the nature of the incentives offered to adolescents and the extent to which adolescents not only enroll as participants in non-therapeutic research studies but are also retained throughout the length of the studies.

Information about the nature of incentives is equally useful for determining its effects on the educational value for adolescents who participate as research subjects, as well as for cultivating developmental abilities for altruistic actions regardless of the material incentives that may have enticed their

ROUNDTABLE 35, 62 (1998). See also E. Donald Elliott, *The Evolutionary Tradition in Jurisprudence*, 85 COLUM. L. REV. 387, 388 (1985) (recognizing laws' dependence "on science as well as other disciplines for the knowledge and data with which legal doctrine is shaped").

²⁰⁷ See, e.g., Gans & Brindis, *supra* note 178, at 308-312 (evaluating ubiquitous conditions for conducting adolescent health research, including the advantages and disadvantages of each).

²⁰⁸ See generally Highet, *supra* note 154.

²⁰⁹ See *supra* notes 92-93 and accompanying text.

²¹⁰ See Scherer et al., *supra* note 64. See also *supra* notes 71-75 and accompanying text.

participation. Issues such as how adolescents learn about the potential for research participation (e.g., schools and related activities), what motivates them to follow-up, and whether they are more likely to seek out research participation in the absence of parents all require exploration.

Consent-related issues likewise merit scientific and social-scientific exploration, including variables suitable for measuring adolescent decisional capability for non-therapeutic research participation.²¹¹ Empirical evidence is needed about the impact of parental presence on adolescents' decisional capabilities when engaging with investigators, and on the way adolescents perceive their autonomy. Do adolescents participate in research of their own volition regardless of parental consent requirements? Would adolescents' voluntary participation increase in both quantity and quality if they could exercise decisional autonomy? Studies suggest that adolescents demonstrate levels of mature understanding and responsible judgment in the absence of parents;²¹² data further suggests that parental presence inhibits these capabilities in research participation.²¹³ If, for example, additional data supports these findings, then the legitimacy of affording adolescents autonomy for consenting to participation in non-therapeutic research is strengthened.

More study is needed that focuses on the impact of parents in the decisional process in terms of providing guidance to which adolescents are receptive. Would adolescents consult with parents if they had legal autonomy for research participation? Does investigators' encouragement increase the probability of parental consultation prior to adolescents committing and consenting to research participation without decreasing their enrollment? Those questions deserve empirical

²¹¹ See Hartman, *supra* note 123, at 123-124. See also Elizabeth Scott et al., *Evaluating Adolescent Decisionmaking in Legal Contexts*, 19 *LAW & HUM. BEHAV.* 221, 229 (1995) (encouraging context-specific data gathering "so as to provide policymakers with a more precise empirically-based understanding of the ways in which the decision making of adolescents compares with that of adults").

²¹² See, e.g., Hightet, *supra* note 154; Ginsburg et al., *supra* note 68.

²¹³ See, e.g., Cohn et al., *supra* note 89; Meade & Slesnick, *supra* note 93.

scrutiny. Findings from studies of conversations among adolescents, parents, and investigators, wherein adolescents exercise decisional autonomy compared with adolescents acquiescing to parents' decision-making authority about research participation, are similarly salient.²¹⁴

As others have reported, decision-making ability is enhanced when adolescents perceive they are respected and not being judged.²¹⁵ This highlights a need for researchers to optimize adolescent-specific interpersonal skills, in order to foster the ethical principles of respecting research participants and promoting their well-being.²¹⁶ The IOM recommends communicating with adolescents in "developmentally appropriate ways," requiring information about investigators' styles that are well suited to adolescents' amenability for research enrollment.²¹⁷ Ostensibly, there is a need for inquiry into the optimum environments for research recruitment and participation conducive to adolescent independent decision making.

Study of adolescent decisional capacity in non-therapeutic research contexts is also needed to inform and refine variables to gauge vulnerability and its impact on consent. How information is imparted and consent is elicited require scrutiny, including whether vulnerability levels are reduced by the quality of that process or heightened when adolescents are excluded from research participation in the absence of parental consent. Data about variables linked to the quality of interaction with clinical investigators would provide a richer understanding about the relationship dynamic and exploitation potential.

Investigator experiences and perceptions are equally valuable, because researchers interact with adolescents in intimate and, at times, emotionally charged environments and

²¹⁴ See *supra* notes 135-141 and accompanying text.

²¹⁵ Ginsburg et al., *supra* note 116, at 925 (finding that adolescents view condescension as a sign of disrespect).

²¹⁶ THE BELMONT REPORT, *supra* note 20, at 4-5.

²¹⁷ Ginsburg et al., *supra* note 116, at 925. See also *supra* notes 176-178 and accompanying text.

thus should be explored.²¹⁸ This exploration could offer extraordinary insights into how law and policy should evolve toward achieving the IOM's aims and whether a presumptive autonomy model is sensible. Investigators, who are obliged to prevent endangerment to adolescent subjects,²¹⁹ should be vigilant in their responsibilities to ensure confidentiality for research participation, raising testable assertions about procedures and venues conducive for privacy assurances. For instance, information about the timing (e.g., initial recruitment and/or consent stage) and methods for conveying those assurances to adolescents is critical, including how privacy assurances bear on adolescents' conceptualization of their decision-making autonomy and generate perceptions of trust affecting their willingness to participate in research. This is also important for learning more about how researchers should convey confidentiality assurances consistent with a mentorship model that has been shown to strengthen adolescents' interest and trust.²²⁰ Such information is equally valuable for educating investigators about how privacy assurances should be discussed and for determining whether—and on what, if any, bases—confidentiality might be conditional.

Should scientific and social-scientific evidence demonstrate that privacy protections increase adolescents' perceptions of trust that lead to research participation, and that adolescents will likely consult with a parent or guardian either on their own or after encouragement from a clinical investigator, then institutions should craft guidelines to supplement the absence of legislative or judicial pronouncements related to adolescent privacy in research participation. Compatible with the IOM's vision, institutions should also provide education and training for investigators who conduct research with adolescents in order to improve ways in which they relate to adolescents that can reciprocally reduce disparate approaches when obtaining their consent. More information about education and training is

²¹⁸ See also Hartman, *supra* note 123, at 90.

²¹⁹ See *supra* notes 170-175 and accompanying text. See also COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 222-223.

²²⁰ Beier et al., *supra* note 70, at 329-331. See also *supra* notes 179-181 and accompanying text.

desirable to inform clinical investigators' roles and responsibilities for monitoring the conduct of non-therapeutic trials with adolescents, including stages of recruitment, enrollment, consent, and the incidence of adverse events. The safety of adolescent research subjects must not be sacrificed,²²¹ and thus training should include how investigators facilitate trust while encouraging adult guidance preferably from a parent or guardian, consistent with the IOM's objectives.²²²

The importance placed by the IOM and the federal regulations on IRB oversight raises a cluster of issues that invite empirical scrutiny. A critical look at how and the extent to which IRBs evaluate waiver of parental consent is a solid starting point. Given the aforementioned points discussed in relation to IRB determinations about waiver of parental consent,²²³ scrutiny of how IRBs exercise this discretion and the indicia on which they determine that parental consent is inappropriate would be especially informative on the elemental point of IRB effectiveness. For example, this scrutiny can uncover flaws in the discretionary power entrusted to oversight review that tend to thwart the purpose for which it was designed;²²⁴ in the case of adolescents, it can also reveal obstacles that impede their research participation. Although evidence regarding IRB performance in general demonstrates deficiencies, little is known about IRB review of research protocols requiring adolescent participants.

A related question commanding empirical scrutiny concerns IRB composition for overseeing research requiring adolescent participation. Chiefly, should that composition include those with specialized knowledge about research ethics and

²²¹ See COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 222-226.

²²² See also Amy T. Campbell, *Adolescent Decisional Autonomy in Research: Issues in Translating Research into Policy*, 5 AM. J. OF BIOETHICS 78, 79-80 (2005).

²²³ See *supra* notes 100-102 and accompanying text.

²²⁴ For example, panels convened by the Secretary of Health and Human Services to review research not otherwise approvable by IRBs have been shown to falter in achieving the purposes for which they were designed. See *supra* notes 198-199 and accompanying text.

experiences with adolescents? Or should those with expertise in adolescence merely be consulted when a protocol under review requires adolescent subjects? Physicians specializing in adolescent medicine and mental health should sensibly be included.

Pediatric IRB composition generally should reflect specialized knowledge about both child and adolescent subjects, including expertise specific to interpreting the regulations for optimal adolescent inclusion. For example, interpreting and implementing parent consent/minor assent provisions in the absence of confidentiality protections may be ethically sound when the participants are children but improvident when they are adolescents, leading to potentially impenetrable barriers for inclusion and possibly paralyzing adolescent participation. While this information would be instructive in terms of how institutional boards reviewing research can be informed and refined in relation to adolescents, institutional experiences with IRBs and perceptions of those serving on IRBs should be known prior to any definitive policy determinations about IRB reform and review of research protocols that require adolescent participation.

Scientific and social-scientific data that inform those issues serve as a precursor to shaping a sensible research policy responsive to the needs of adolescents. This Article has discussed the IOM's objectives, addressed the obstacles posed by the federal regulations for achieving those objectives, and, perhaps more importantly, explored the issues germane to adolescent research participation by fleshing out the testable assertions raised by issues in recruitment, consent, and institutional oversight for empirical examination.

B. RECOMMENDATIONS FOR POLICY AND LAW

Empirical study of the issues specific to adolescent research involvement would catalyze policy for devising a cohesive legal regime through regulatory reformation and/or state statutory schemes. This information can both shape and steer revisions to the existing federal regulations or, alternatively, provide a basis for crafting separate regulations for conducting adolescent research. Meanwhile, regulatory requirements and ambiguities should not be construed to hinder adolescent participation in non-therapeutic research, thwarting the IOM's objectives.

Moreover, states could enact statutes to clarify and supplement the application of regulatory provisions to adolescent research participation.²²⁵ These statutes could set forth a presumption of adolescent decision making about participation in non-therapeutic research, subject to an investigator's capacity assessment if a particular adolescent appears to be immature and less capable. In assessing adolescents' capacity, investigators could be guided by factors that have been identified and substantiated by scientific evidence. Should an investigator find that an adolescent lacks decision-making capability, parental involvement and consent would be required.

The plausibility of divergent state approaches to adolescent research autonomy, however, assails the necessity for elucidating policy at the national level and reforming the federal regulatory regime. This reformation could reflect a presumptive adolescent legal autonomy for non-therapeutic research participation, thereby enabling the states to complement the regulations with statutes that further federal policy and also guide privately funded research within the state to ensure decisional autonomy protections for adolescents.

Legal policy must foster research integrity with adolescents while furthering the IOM's objectives to optimize adolescent participation in order to generate knowledge beneficial to this age group as well as to benefit the adolescent participants. While not setting forth an adolescent decisional rights archetype for research participation, this Article nonetheless suggests that legal policymakers dismantle barriers inhibiting adolescents' decisional abilities about participating in non-therapeutic research. Adolescents are not categorically excluded from participating in non-therapeutic research but specific legal policy is required for minimizing obstacles and maximizing inclusion.

V. CONCLUSION

The IOM introduces its report by quoting Goethe: "Knowing is not enough; we must apply. Willing is not enough; we must

²²⁵ See COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, *supra* note 12, at 5.

do.” Now that issues central to the IOM’s imperative of increasing adolescent research participation are known, scientific and social-scientific investigation of those issues must be done and applied for legal policy analysis. This Article adds depth to the IOM’s aims and advances its imperative by discussing the issues commanding attention in adolescent non-therapeutic research, delineating points for empirical study, and devising recommendations for law.

Devising a legal framework that promotes the ethical conduct of research with adolescents and prevents impediments to their inclusion allows laws to adequately address adolescents and their distinct needs apart from the needs of children. By enabling adolescents to participate increasingly in research, the IOM’s goals for valid, reliable findings about drug effects and customized medical interventions for this age group may be realized. Furthermore, laws affording adolescents decisional autonomy for non-therapeutic research participation, whether achieved through regulatory reformation or state statutory enactments, could advance the policies of knowledge acquisition with minimal harm to those participating in research that justify human experimentation.

To this end, overarching issues of recruitment, consent, confidentiality, researchers’ roles and responsibilities, and oversight review command incisive inquiry. Empirical evidence would inform these issues, thereby enabling comprehensive analysis about conducting research with adolescents, calibrating policy, and reconfiguring legal standards that optimize the ethical conduct of research with adolescents. Data on those issues would inform legal policy analysis prior to any definitive determinations by providing a factual basis for determining why a particular policy approach may be preferable in advancing the IOM’s goals and responding to adolescents’ needs. The process of extrapolating from existing ethical and regulatory regimes designed for conducting research with adults and children is insufficient.²²⁶ It hinders legal policy analysis toward advancing a research agenda for adolescents envisaged by the IOM. Legal policy development is likewise hampered by the scarcity of

²²⁶ See also Campbell, *supra* note 222, at 79 (noting that tailoring federal regulations for conducting research with adolescents “does not translate well into broad-based policy”).

scientific and social-scientific study needed to inform issues specific to adolescent research involvement, which remains a work in progress.²²⁷

In short, the National Academies' imperative for increasing adolescent research participation contributes to discourse and debate about the ethical conduct of human subject experimentation. This Article advances this imperative by identifying issues attendant to adolescent non-therapeutic research involvement that necessitate in-depth inquiry, and by sorting out precise points for empirical study in order to inform legal policy analysis. Given the complexities that compel attention when conducting research with adolescents, the word from the Academies should not be the last.

²²⁷ See Hartman, *supra* note 123, at 133.