

One Size Doesn't Fit All:

Showing Adolescents the Respect They Deserve as Research Participants

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ABSTRACT

In this paper I argue that adolescents should be asked directly for informed consent to participate in minimal risk research about behaviors that impact adolescent health and well-being. I demonstrate that parental permission for an adolescent's participation in such research does not provide additional protection from research risk and is disrespectful of the adolescent's capacity to choose based on his own assessment of the risks, discomforts or inconveniences of participation. Requiring parental permission while merely asking an adolescent to "assent" also undermines the moral benefit he might attain because it denies him the opportunity to voluntarily make a contribution of his time and effort for the benefit of others. I show that the federal regulations governing research with children are based on an inappropriate "one size fits all" perspective that treats all kinds of research and all children under the age of 18 similarly in regard to the requirement for parental permission. The regulations should be amended to recognize adolescents as a distinct population, "characterized by developing cognitive capacities

in addition to judgment.”¹ While adolescents may need additional protections as research participants, IRBs need to ask whether parental permission is an appropriate protection, or whether there should be other protections that are tailored to the actual vulnerabilities of adolescents. Finally, I discuss the possibility that adolescents may benefit from being asked to share their stories with research investigators. Marginalized youth, including those who have mental health problems, drug addiction or other stigmatizing conditions, may gain a sense of self-respect from being asked to contribute their personal experiences to help other youth in the future. Allowing youth to participate in observational research projects that are carefully constructed to provide appropriate protections may also provide adolescents with an opportunity to obtain guidance and support from adult professionals who are sympathetic, nonjudgmental, and experienced with adolescents’ problems and behaviors.

¹ Society for Adolescent Medicine (1995). Guidelines for Adolescent Health Research. Journal of Adolescent Health 17:264-269.

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1.0 INTRODUCTION

For 20 years I was a research coordinator for longitudinal studies of children and adolescents with serious emotional disturbances including Attention Deficit Hyperactivity Disorder, Conduct Disorder and Substance Use Disorders. The youth I interviewed for these research projects were diverse in terms of age, race, cognitive abilities, and socio-economic background. I generally felt confident that they understood what I was asking them to do, which was to complete psychiatric interviews, cognitive tests, measures of reading skills and other educational assessments, and answer questions about their behavior. I was also generally confident that they were capable of understanding the potential risks of participation in the research, which were limited to privacy risks and potential discomfort or embarrassment answering personal questions. I made sure to tell all of the children how much we appreciated their participation in the research, because the doctors who write books about kids' problems can't do it by reading other books; they have to talk to kids themselves. I told them that they were the experts on what it is like to be a kid, and we needed them to teach us so we could help other kids in the future. In other words, I told them that they were respected and appreciated for their contribution to our research.

All of the youth had the permission of a parent to participate in the research, and in most cases, after providing her permission, the parent would tell me that it was up to the child himself whether or not to participate. On occasion however, a youth would be less than enthusiastic

about participating in the research but his parent would insist, and a full scale family argument would ensue. I found these incidents to be quite discomfiting; while I sincerely wanted the child to participate because I was committed to the success of the research project, I didn't relish having to interview an unwilling participant; it didn't seem like the right thing to do. I was also well aware that the quality of an unwilling child's responses would be quite suspect. So in private, before beginning each child's interview, I would tell him that it was entirely his choice whether or not to participate and that it was not up to his mother to decide. I would also assure him that it wouldn't bother me or hurt my feelings if he said "no," and no one would be angry at him. In those few cases where a parent insisted that the child participate, telling him privately that he could go against his parent's wishes made me a bit uncomfortable, as if I was condoning the child's disobedience. But telling all the children and especially, the reluctant children, that it was ultimately their choice whether or not to participate seemed to me to be an important acknowledgment that the child, (not his parent), was being asked to make a contribution to the research in the form of his time and attention, and that this contribution needed to be made by him voluntarily.

After substantial reflection on both my interactions with these young people and on the regulations governing human subjects' protections, I have come to believe that in order to show them the respect they deserve, adolescents should be asked directly for informed consent to participate in minimal risk research about behaviors that impact adolescent health and well-being. Requiring parental permission for an adolescent's participation in such research is inappropriate because it does not provide additional protection from research risk and is disrespectful of his capacity to choose based on his own assessment of the risks, discomforts or inconveniences of participation. Requiring parental permission while merely asking an

adolescent to “assent” is disrespectful of adolescents’ developing autonomy, and undermines principles of research ethics, including respect for persons, beneficence and justice. It also undermines the moral benefit an adolescent might attain because it denies him the opportunity to be altruistic by virtue of volunteering on his own behalf.²

This project begins with my recognition that the federal regulations governing research with children are based on an inappropriate “one size fits all” perspective that treats all kinds of research and all children under the age of 18 similarly in regard to the requirement for parental permission. I make the case that the regulations should be modified to recognize the different kinds of risks posed by various types of research, and should be amended to recognize adolescents as “a distinct group, between childhood and adulthood, characterized by developing cognitive capacities in addition to judgment.”³ Parental permission should not be required for adolescents’ participation in many types of minimal risk, behavioral research for two different sets of reasons. The first concerns adolescents’ autonomy and well-being. The second concerns the potentially negative repercussions the requirement for parental permission has on the quality of the science, including the generalizability of the research results.

Adolescents should be asked to provide direct consent to research that involves risks that they are developmentally capable of comprehending. These risks should be limited to those that would primarily affect the adolescent’s present self: the risk of discomfort or embarrassment answering personal questions, the risk that their responses to sensitive questions may be revealed to others, boredom when completing cognitive assessments, slight pain and bruising from a blood draw, for example. I am not arguing that all adolescents be treated as fully

²Hartman, R. G., (2006). Word from the Academies: A primer for legal policy analysis regarding adolescent research participation. *Rutgers Journal of Law and Public Policy* 4(1): 151-199, p. 169-170.

³ Society for Adolescent Medicine (1995). Guidelines for Adolescent Health Research. *Journal of Adolescent Health* 17:264-269.

autonomous adults, or that they do not need to be afforded additional protections as research participants. If they are to be asked to provide direct consent to research participation, the informed consent process must be tailored to their level of literacy, and extra care should be taken to ensure that adolescents understand potential risks to their privacy, especially when sensitive information is being collected. This is also not to say that the mature judgement of a parent who has her child's best interest foremost in her mind is not an appropriate protection for an adolescent to participate in clinical or experimental research that poses greater than minimal risk. Parental permission may also be appropriate to protect adolescents from certain kinds of non-physical research risks that the adolescent himself may not be capable of recognizing. Examples might include research involving the return of genetic information that could jeopardize his present or future relationships with other family members or research that involves measures of academic abilities that may affect his participation in current or future educational opportunities. But behavioral research that involves the systematic collection of information may meet the standard for adolescents to provide direct consent as long as appropriate protections are in place.

For the purposes of this project, I will use the terms "behavioral" or "observational" research to refer to the sort of studies that I have in mind as appropriate for adolescent direct consent, though interaction with the investigator may be involved and research questions may be about things other than behaviors (e.g., attitudes, values, beliefs, and experiences). Research meeting these criteria may include cross-sectional surveys and questionnaires, qualitative research including focus group and cognitive or open-ended interview techniques, research that involves psycho-social, educational and behavioral assessments, and cohort, longitudinal or prospective research studies. In general, the research I refer to as "behavioral" or "observational

would fall under category 7 of the types of research that can be approved by an IRB under “expedited” (rather than “full board”) authority under the federal regulations at 45 CFR 46.110: “Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.”⁴

Section 1 provides an overview of the normative framework for research with adolescents. In section 2, I review the additional protections required for research involving children at Subpart D of the federal regulations (section 2.1) and demonstrate how the authors of the Belmont Report provided for the ethical inclusion of children and other ‘vulnerable’ individuals by including provisions for the protection of individuals who are not fully capable of exercising autonomy in regards to research participation (section 2.2). In section 2.3, I examine the ongoing debate that began with the exchange between Paul Ramsey and Richard McCormick in the 1970’s over whether it is ever ethical to include children in non-therapeutic research. Section 3 challenges the presumption that all children are “prerational” and “pre-moral” and therefore incapable of making autonomous decisions about research participation. I present empirical evidence from recent research on adolescent brain development that demonstrates that adolescents possess cognitive abilities and the capacity to make important decisions comparable to that of young adults. I also discuss why the current regulatory requirement for parental permission and child assent is not sufficiently respectful of adolescents. Section 4 addresses the importance of conducting behavioral research with

⁴ U.S. Department of Health and Human Services, Code of Federal Regulations at 45 CFR 46.110 <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.110>

adolescents, and provides evidence that the requirement for parental permission seriously impedes such research. I discuss how the current federal regulations inappropriately over-protect adolescents and should be amended to recognize adolescents as a distinct population with regard to participation in behavioral research. Finally, I discuss the possibility that adolescents who participate in behavioral research may derive benefit from their participation in several important ways.

2.0 NORMATIVE FRAMEWORK FOR RESEARCH WITH ADOLESCENTS

In this section I examine the additional protections required by the federal regulations at 45 CFR 46 Subpart D for children in research that include limitations on the amount of risk children may be exposed to, and the requirements for parental permission and child assent. I examine how the authors of the Belmont Report provided an ethical framework to support the conduct of nonbeneficial research with vulnerable individuals who were deemed incapable of providing consent. I then discuss the ongoing debate over whether it is ever ethical to include children in research that does not hold out the prospect of a direct benefit.

2.1 FEDERAL REGULATIONS AT 45 CFR 46 SUBPART D

The federal regulations specify the additional procedures required to protect “vulnerable” populations from the risks posed by research participation. Subpart B addresses protections for pregnant women, fetuses and neonates. Subpart C addresses protections for prisoners. Subpart D addresses additional protections for children involved as subjects in research. The regulations define children as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the

research will be conducted.”⁵ IRBs may only approve research with children if it “satisfies the conditions of all applicable sections” of Subpart D.

2.1.1 Risk - Benefit ratio as the basis for IRB approval

According to the regulations, an IRB may approve research involving children only if it first determines that the research meets one of three definitions of risks and potential direct benefit. The first category is defined at 46.404: Research not involving greater than minimal risk. This is research that falls under the definition of ‘minimal risk’ at 46.102: that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” Most, if not all, behavioral research would fall within this determination, depending on the judgement of the individual IRB reviewing the study, since the potential risks of behavioral research as defined in the introduction are limited to mild emotional upset or embarrassment, and the risk of a breach of privacy.⁶ Because risks are so low, research deemed to fall under the 46.404 designation may be conducted with children even if there is no direct benefit to the subjects. But even if risks are “minimal,” and “not greater in and of themselves than those ordinarily encountered in daily life” they may still exist. Ruiz Canela and colleagues point out that the primary difference between experimental and observational research with adolescents is that the risks of observational research are related to the information obtained rather than any risk of physical harm. Distinguishing between “risk of

⁵ U.S. Department of Health and Human Services, op cit., <http://www.ecfr.gov/cgi-bin/text-idx?SID=ce4f9183a5e6a408d163ce5d1d8535c5&mc=true&node=sp45.1.46.d&rgn=div6>

⁶ In section 4.2 I discuss the possibility that when IRBs deem some kinds of behavioral research with adolescents as greater than minimal risk, they do so inappropriately

harm” and “risk of discomfort,” these authors note that harm and discomfort may be psychological or physical, and assert that the risks of observational research “can be bidirectional because information can have a negative impact both when adolescents are exposed to sensitive questions and when their answers to these questions are known by their parents or other persons.”⁷ Whether adolescents are actually harmed by being asked “sensitive questions” is questionable, though these authors caution that observational research with adolescents is minimal risk only if the questions are “concordant with the age, family, social, and cultural characteristics” of the adolescents who will be included, and suggest that parents and community representatives (presumably adults), may be able to advise researchers on what is appropriate.⁸ But it is difficult to imagine what sorts of questions could cause real psychological harm to adolescents, and more to the point, it is unlikely that adults would be able to accurately identify the sorts of questions that would actually harm adolescents. In section 4, I explore the possibility that IRBs tend to over-protect adolescents by making unrealistic estimations of the potential risks of asking questions about sensitive topics. The risk that an adolescent’s responses to sensitive questions could become known to others and cause him harm is a risk that should be taken seriously, and youth are typically quite capable of understanding the risk and making a decision about whether to expose himself to this risk.⁹

The second category is 46.405: Research involving greater than minimal risk, but presenting the prospect of direct benefit for the individual subject as long as the IRB finds that the risk is justified by the anticipated direct benefit that is at least as favorable to the subjects as

⁷ Ruiz-Canela, M., et al., (2013). Observational research with adolescents: a framework for the management of parental permission. *BMC Medical Ethics*, 14(2): <http://www.biomedcentral.com/1472-6939/14/2>, p. 6

⁸ Ibid.

⁹ Navratil, J. et al., (in press) Involving Youth Voices in Research Protocol Reviews. *American Journal of Bioethics*.

that presented by available alternatives outside of the research context. Third, is research defined at 46.406: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. An IRB may approve research that meets this definition if it finds that the risk represents no more than a minor increase over minimal risk, the research interventions or procedures involve experiences that are similar to experiences the subjects have had in their actual or expected medical, dental, psychological, social, or educational situations, and that the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition "which is of vital importance for the understanding or amelioration of the subjects' disorder or condition." A fourth category of research that may be done with children cannot be approved by an IRB, but requires review and approval of the Secretary of the U. S. Department of Health and Human Services: 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.¹⁰

A number of commentators have criticized the regulatory definitions of allowable risks and potential benefits for research involving children. Koppleman, for example, has noted that many key concepts governing pediatric research are so poorly defined in the federal regulations that individual IRBs have extremely wide latitude to make determinations of risks and benefits that vary quite significantly, both among different IRBs and among individual IRB committees within the same institution.¹¹ Wendler and Emanuel point to the absence of a systematic standard for assessing what research procedures would pose a "minor" increase over minimal

¹⁰ U.S. Department of Health and Human Services, op cit.

¹¹ Koppleman, L. (2006). Children as research subjects: Moral disputes, regulatory guidance, and recent court decisions. The Mount Sinai Journal of Medicine 73(3): 596-604, p. 600.

risk, leaving IRB members with nothing but their own intuitions and perceptions when making these assessments. “Yet,” they comment, “individuals make systematic errors when assessing risks based on their own perceptions. They focus on characteristics of activities that do not reliably correlate with their risk level, including familiarity with the activity, perceived level of control over the activity, and reversibility—rather than severity—of the activity’s potential harms.”¹² Shah and colleagues also note that IRBs appear to rely on intuition alone when determining risk levels for pediatric research, resulting in inconsistent decisions both within and among IRBs.¹³ Miller and Weijer point out that “in the absence of a conceptual framework, it is difficult to see how the IRB can effectively fulfill its mandate.”¹⁴ A 2001 report from the Office of Human Research (OHRP) Committee found that while an IRB’s assessment of the risks and potential benefits of research is central to determining whether that research is ethically acceptable, this assessment is difficult because there are no clear criteria provided in the regulations for IRBs to use when judging whether the risks of research are reasonable in relation to the potential benefits to individual research participants or benefits that will accrue to society.¹⁵ In other words, the regulations at Subpart D leave far too much to the discretion of IRB reviewers. I contend this is equally true for the requirements for parental permission and child assent, as demonstrated in the next section.

¹² Wendler, D. and Emanuel, E. J., (2005). What is a ‘minor’ increase over minimal risk? Journal of Pediatrics, 147:575-8, p. 577.

¹³ Shah, S. et al., (2004). How do Institutional Review Boards apply the federal risk and benefit standards for pediatric research? Journal of the American Medical Association 201(4): 476-482.

¹⁴ Miller, P. B., and C. Weijer, (2000). Moral solutions in assessing research risk. IRB: Ethics and Human Research 22(5): 6-10.

¹⁵U.S. Department of Health and Human Services, Office of Human Research Protections (2001). Protections for Children in Research: A Report to Congress in Accord with Section 1003 of P.L. 106-310, Children’s Health Act of 2000.

2.1.2 Requirement for parental permission and child assent

The federal regulations at 45 CFR §46.116 specify that “no human being can be involved as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.”¹⁶ The regulations at 45 CFR 46.408 require that when reviewing research involving children, IRBs determine that “adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.” The regulations also require that “adequate provisions are made for soliciting the permission of each child's parents or guardian.”¹⁷ Because children lack the *legal* capacity to consent, the child’s agreement to participate must be supplemented by the permission of their parents or legal guardians as the child’s ‘legally authorized representative’. Whether this dual requirement for parental permission and child assent is ever an appropriate replacement for the fully informed consent required for adult participation in research is controversial,¹⁸ and is discussed in section 3.3.

Requiring a child’s assent for participation is supposed to acknowledge the child’s status as a future autonomous agent. The thinking is that while the child’s autonomy is “diminished” by virtue of youth, she may nevertheless have preferences or interests that ought to be respected. Protection of the child whose autonomy is “diminished” is supposed to be provided by requiring parental permission, presumably because a parent knows what is best for her child and will act according to the child’s best interest. As discussed in the previous section, protection is also supposed to be provided by the requirement that IRBs allow children to be

¹⁶ U.S. Department of Health and Human Services, op cit., 45cfr46.html#46.408

¹⁷ Ibid.

¹⁸ See Wendler, D. S., and Shah, S., (2003). Should children decide whether they are enrolled in nonbeneficial research? The American Journal of Bioethics 3(4): 1-7 and peer commentary articles in the same issue of the journal

exposed to research risks only under limited circumstances. Once the IRB has determined that the risks and benefits of the research are acceptable, the protective role shifts to the investigator, who is obliged to inform the parent of these risks and any potential benefits. The parent or parents then assume responsibility for providing permission only after these other individuals fulfill their protective role. Only after all of these other agents provide their “consent” is the child then asked to “assent” to participation, defined in the regulations as “a child's affirmative agreement to participate in research.” The definition in the regulations emphasizes that assent is a positive, not a negative, requirement: “Mere failure to object should not, absent affirmative agreement, be construed as assent.”¹⁹

IRBs are charged with determining whether the children to be included in a particular research study are capable of providing assent by considering “the ages, maturity, and psychological state of the children involved.” IRBs are to make this judgement “for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.” As I discuss in section 3, it is unclear whether IRBs spend a great deal of time and effort determining whether assent should be sought either from children in protocols generally or from individual children in a particular protocol under review; I also suggest that the requirement for assent is not taken seriously. Stroustrup and colleagues surveyed IRB members and found significant deficits in members’ knowledge of the regulatory and ethical requirements for conducting research with children.²⁰ Kimberly et al. found that IRBs exhibited

¹⁹ U. S. Department of Health and Human Services, Office of Human Research Protections, Code of Federal Regulations: Title 45 Public Welfare: Part 46: Protections of Human Subjects.
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402>

²⁰ Stroustrup, A., Koretsky, S. and Joffe, S. (2008). Knowledge of regulations governing pediatric research: A pilot study. IRB: Ethics and Human Research 30(5): 1-7.

substantially different standards for requiring children’s assent to participate in research.²¹ The regulations specify that an IRB may determine that assent is not required if “the capability of some or all of the children is so limited that they cannot reasonably be consulted *or* that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research. ...Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116.”²²

For research that meets the conditions for approval at 46.404 (i.e., research involving no more than minimal risk) and the conditions for approval at 46.405, (i.e., that involving greater than minimal risk but holding out the prospect of a direct benefit to the child), the IRB is charged with determining whether the permission of one or both parents is sufficient. But for research that meets the conditions described in 46.406 and 46.407 where there is greater than minimal risk and no prospect of a direct benefit to the child, both parents must give their permission “unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.” Requiring the consent of both parents is presumably intended to provide additional protection to children prior to enrolling them into high risk, non-beneficial research, but what the regulations mean by the second parent not being “reasonably available” is left open to interpretation.²³ To

²¹Kimberly, M. B., et al., (2006). Variation in Standards of Research Compensation and Child Assent Practices: A Comparison of 69 Institutional Review Board–Approved Informed Permission and Assent Forms for 3 Multicenter Pediatric Clinical Trials. *Pediatrics* 117(5):1706-1711, p. 1710.

²² U.S. Department of Health and Human Services, Code of Federal Regulations, op cit.

²³ The Federal Regulations at Subpart D are entitled, “Additional Protections for Children Involved as Subjects in Research.” The word “protection” reappears only once in the actual regulations, at 46.408: “...if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or

demonstrate how seriously IRBs take the requirement for parental permission, the executive committee of the University of Pittsburgh IRB recently approved guidance that requires investigators to make significant efforts to contact a second parent, unless “the parent who is present can provide documented proof that s/he has sole legal responsibility for the child... (including) a copy of the court order granting sole custody and legal decision-making authority to the parent who is present, including sole legal authority to make medical decisions for the child or a copy of the birth certificate listing ‘unknown’ for the other parent.” The guidance defines a parent who is “not reasonably available” as “one who cannot be contacted by phone, email, mail or fax: for example, a parent on active military duty. If the other parent is ‘not available’ simply because s/he is at work, traveling, or caring for other children, or even if s/he lives in another city or state, it is the investigators’ responsibility to attempt to obtain that parent’s permission before enrolling the child in the research.”²⁴ The investigator is instructed to make a “concerted effort” to contact the absent parent at home, at work, by phone, fax or email. “The amount of time and effort that investigators should devote to contacting an absent parent will vary depending on the individual circumstances and the constraints posed by the research protocol. However, investigators must have standard operating procedures in place for contacting the absent parent, and all such efforts must be documented in the research record.”²⁵

guardian permission is not a reasonable requirement to protect the subjects.” See <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408>

²⁴ University of Pittsburgh Institutional Review Board Executive Committee (2014). Guidance: Not reasonably available. http://www.irb.pitt.edu/sites/default/files/Guidance/ReasonablyAvailable_2.19.2015.pdf.

²⁵ Ibid.

2.1.3 Waiver of parental permission

The regulations do provide several provisions that allow adolescents to provide their own direct consent for participation in research, but as with the regulatory language on child assent, these provisions are ill defined and left to the discretion of IRBs. The regulations define children as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted.” Research with adolescents related to STDs, contraception, mental health, and substance abuse, for example, would appear not to require parental permission if under applicable state law an adolescent can obtain treatment for these conditions without a parent’s permission. But state laws regarding a minor’s right to consent or refuse medical treatment are very complicated. Vukadinovich notes that while these laws “attempt to balance the rights and obligations of parents and guardians against the access and privacy rights of minors, complicated state statutory schemes often fail to simultaneously address those contrasting goals in a consistent and uniform manner. The result is a confusing set of seemingly arbitrary and sometimes conflicting provisions that require the detailed attention of healthcare providers to ensure legal compliance.”²⁶ In addition, state laws related to adolescents’ research participation are essentially nonexistent.²⁷ In the absence of clear guidelines, IRBs may interpret the definition of a child given in the regulations to mean that an adolescent may consent to research that involves *only* those procedures or treatments for which an adolescent can consent to receive as a patient. If the research involves any procedure that falls outside of those “treatments,” (for example, a

²⁶ Vukadinovich, D. M., (2004). Minors' Rights to Consent to Treatment: Navigating the Complexity of State Laws American Health Lawyers Association, Journal of Health Law 37(4): 667.

²⁷ Hartman, RG (2006). Word from the Academies: A primer for legal policy analysis regarding adolescent research participation. Rutgers Journal of Law and Public Policy 4(1): 151-199, p. 160.

study about the acceptability of a form of HIV testing that includes a demographics questionnaire to collect information on household members such as family income, race and educational status), the IRB may decide that the adolescents are not “adults” for the purpose of their participation in this research and are therefore not able to provide their own “consent.”

The regulations specify that an IRB may determine that parental permission is not a “reasonable requirement” to protect child subjects, and waive parental permission “provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.” The regulations cite the example of “neglected or abused children” for this type of waiver, and guidance documents suggest additional circumstances: “children whose parents are legally or functionally incompetent.”²⁸ Research with adolescents who are homeless, gay or transgendered, or those who do not live with a biological or legally adoptive parent but are being cared for by other relatives, may qualify for a waiver of parental permission under these criteria, as long as “appropriate mechanisms for protecting the children” are substituted for parental permission. Studies to determine IRBs’ utilization of this alternative that examine IRB members’ attitudes about this waiver and explores their views about what “appropriate mechanisms for protecting the children” should be applied should be conducted.

Finally, the regulations specify that an IRB may alter or waive the requirement for informed consent as long as 1) the research involves no more than minimal risk; 2) the waiver

²⁸U.S. Department of Health and Human Services, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1977). Research involving children: Report and recommendations.

will not adversely affect the rights or welfare of subjects; 3) the research could not practicably be carried out without waiver or alteration; and 4) whenever appropriate, the subjects will be provided additional information after participation (45 CFR 46 116). The criteria for a waiver of informed consent may be applied to justify a waiver of parental permission for a child's participation in many kinds of minimal risk (e.g., observational or questionnaire) studies.

Many IRBs appear to be quite reluctant to waive parental permission, even in circumstances where there is little reason to believe that a parent's involvement in the decision to participate would offer to the child any relevant protection from the risks of the research. In a survey of IRB chairpersons to determine practices concerning consent for adolescents in research, Mammel and Kaplan found that 69% of the IRBs they surveyed required parental permission for *all* research with minors described in twelve hypothetical research protocols that involved varying degrees of risk.²⁹ Only 29% of IRBs would waive parental consent for an anonymous survey of adolescents about HIV status. Still, these investigators found that when "the scenarios are ranked from most to least likely to have parental consent waived, a hierarchy emerges that may represent a continuum from minimal risk to increasing risk, or from minimally intrusive or invasive to more significantly intrusive/invasive: anonymous survey, interview, use of blood from a venipuncture specimen that was already being obtained, pelvic examination, venipuncture purely for research purposes, drug already in use for pediatrics or in pediatric trials, urethral swab, study with identifiers, and drug in adult trials."³⁰ The study also found that more than half the IRB chairs surveyed were in favor of changes to the regulations that would enable adolescents to consent to research involving surveys, venipuncture, or health

²⁹ Mammel, K. A., and Kaplan, D. W. (1995). Research consent by adolescent minors and Institutional Review Boards. *Journal of Adolescent Medicine*, 17:323-330, p. 326.

³⁰ *Ibid*, p. 328.

conditions for which minors may consent to treatment. This finding is disturbing, since the regulations already allow for much of this type of research without the requirement of parental permission.

2.2 THE BELMONT REPORT

Recognizing the importance of research with individuals who are vulnerable the authors of the *Belmont Report* included within the principle of “Respect for persons” two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.”³¹ Defining autonomy as the capacity to deliberate about “personal goals and acting under the direction of such deliberation,” the Belmont authors acknowledge that judging an individual’s capacity for “self-determination” is not a simple matter. Whether impaired by immaturity, cognitive impairment, illness, “or circumstances that severely restrict liberty,” individuals deemed to have diminished autonomy should be protected, but the exact nature and extent of these protections should be based on the circumstances at hand and correspond to the risks and potential benefits of the research. The nature and extent of additional protections must also be based on a judgment about the extent of the individual’s incapacity: “Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection

³¹ U.S. Department of Human Services, (1979). National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report. <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

beyond making sure they undertake activities freely and with awareness of possible adverse consequence.”

The Belmont authors stressed that the judgment that a particular individual lacks the capacity for autonomy “should be periodically reevaluated and will vary in different situations.” A comatose adult enrolled into a research study with the proxy “consent” of his legally authorized representative should be asked to provide his own consent to continued participation in the research once he regains consciousness. An elderly patient with dementia, approached about participation in a clinical trial to test the efficacy of an experimental drug in preventing further memory loss, may require the added protection of having her adult daughter consider the potential risks and benefits of participation and provide proxy consent. The elderly patient may then be allowed to enroll provided she is willing to participate and provides her own “assent” to each of the study procedures. The same individual, approached about a study to evaluate the effect of a mild exercise routine on mood and quality of life may have no need to consult her daughter before deciding whether or not to participate. She may be quite competent to understand the potential risks, discomforts and inconveniences posed by participation in the exercise study, as well as the potential benefits, given an appropriate consent process tailored to her current level of cognition. She should not be asked to merely “assent” to participation, and the investigators should not be required to obtain her daughter’s proxy signature on the research consent document. With regard to those with diminished autonomy, the Belmont Report affirms that the “extent of protection afforded should depend upon the risk of harm and the likelihood of benefit.” The authors of the report also acknowledge that respecting persons, “in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.”

While respect for persons requires that individuals with diminished autonomy are entitled to protection, exactly what protections are appropriate in each case is left open to considerations based on the individual circumstances. The assumption that all children are “both vulnerable subjects who need protection from research risks and therapeutic orphans who have been denied access to the benefits of research”³² posed a serious predicament for the members of the first Presidential National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In the Mid-1970s, revelations of the abuse of children and other vulnerable subjects by researchers were featured prominently in the media. Also in the Mid-1970s, the federal regulations governing DHHS sponsored research were being drafted to provide explicit ‘additional protections’ for children in research in order to recognize children as vulnerable research subjects but allow pediatric research to proceed.³³ In 2004, the former Director of the National Institute of Child Health and Human Development at the National Institutes of Health, Duane Alexander, was interviewed as part of an oral history of the Belmont Report. He noted that, as a pediatrician,

I had a vested interest in the issue of research on children. I had spent several years here at NICHD involved in research of various types...and was very keenly professionally and personally committed to making sure that research with children would not get banned, that it would be allowed to go forward in an ethically acceptable way so that we could gain the knowledge we needed so badly to improve their health and development and well-being. There was great concern at the time that impediments could be placed in the way of getting this research on children done, to the detriment of children. Sometimes we protect people to their harm. And there was a very real risk that this could have happened with children; with other population groups; particularly, others that couldn't give consent.”³⁴

³² Kodish, E., (2005), Ethics and Research with Children. Oxford University Press: New York, p. 3.

³³ Ibid, p. 6.

³⁴ U.S. Department of Human Services, National Institutes of Health, Office of Human Research Protections www.hhs.gov/ohrp/archive/docs/InterviewAlexander.doc

The imperative to conduct research with children and other “vulnerable” groups prevailed over concerns about whether such research treats them merely as a means to an end. The debate over whether including children in non-beneficial research can be justified, however, continues to the current day.

2.3 THE ETHICS OF RESEARCH INVOLVING CHILDREN

“The voluntary consent of the human subject is absolutely essential. This means that the person should have legal capacity to give consent.”³⁵ The first principle of the Nuremberg Code set the stage for the ongoing debate over whether it is ever ethical to include children (defined as anyone under the legal age of consent) in research. If the central requirement for the ethical conduct of research is the fully informed consent of a competent individual who is free to exercise his or her own will without restriction and free from duress, then research involving an individual of any age who does not meet all of these prerequisites for informed consent is ethically problematic. Because children are presumed to lack the capacity to consent, some have argued that it is never ethical to use them as human research subjects unless the research offers a direct benefit. In Ramsey’s view: “To attempt to consent for a child to be made an experimental subject is to treat a child as not a child. It is to treat him as if he were an adult person who has consented to become a joint adventurer in the common cause of medical research.”³⁶ For

³⁵ Nuremberg Code. <http://history.nih.gov/research/downloads/nuremberg.pdf>

³⁶ Ramsey, P., (1970) The Patient as Person Yale University Press: New Haven, p. 35

Ramsey, involving children in non-therapeutic research can never be morally justified because parents and doctors have a fiduciary responsibility to them, and allowing them to participate in research that entails some risk with no prospect of direct benefit is a breach of this responsibility.

McCormick countered Ramsey's position with a natural law argument that there are "certain identifiable valuables that we ought to support... because they are definitive of our flourishing and well-being."³⁷ In his view, parental consent for a child's research participation is valid if it is viewed as a presumption of the child's willingness to participate because he *ought* to do so. To argue as Ramsey had that using children as research subjects is using them merely as a means to an end presumes an atomistic view of human existence, when in reality, humans are essentially social beings. A child's participation in research is consistent with treating the child as an end, understood to mean a social being. Ramsey's response was that using children in non-therapeutic research may serve societal goals, but fails to serve the child's interests. It treats the child as a "small adult" – a moral agent with moral obligations, and imposes a "minimal positive sociability" on children and everyone else – in effect, an enforced Good Samaritanism: "McCormick's argument . . . is quite enough to justify the regimentation of any and all other human subjects into medical research, provided only that they are needed and that the risks are minimal."³⁸

In fact, McCormick does not object to the ethical precept of requiring that everyone participate in research designed to promote future societal good: "That is exactly where my

³⁷ McCormick, R.A., (1976a). Experimentation in children: sharing in sociality. The Hastings Center Report, 6 (6): 41-46, p.42.

³⁸ Ramsey, P. (1976). The enforcement of morals: nontherapeutic research on children. The Hastings Center Report 6 (4):21-30, p.24.

argument leads, indeed exactly where it started....³⁹ He cites his own earlier argument:

At some point, then, our willingness to experiment on children...when risk, discomfort, and pain are minimal or nonexistent points to a duty that we all have to be willing to bear our fair share that all may prosper.... I am not speaking of heroic sacrifices or supererogatory works, which call on and promote individual generosity. I am speaking of the minimal duties that might fall into the more basic category of social justice. If we really expect to, want to, and demand to enjoy the fruits of medical progress, we should be willing to bear our share in the development of this progress. For too long we have been transferring this task to the powerless-the retarded, the poor, the incarcerated. The associated inhumanities are all too clear.⁴⁰

Further, McCormick charged that Ramsey's view ignores the fact that humans are social beings who may act to further social ends. Ramsey's position may protect the child, but does so with no acknowledgement of the sociality of the child, undermining

...not only the overall good of children, but even and eventually of the individual child. The child, when she becomes an adult with children of her own, will-- if she has the good of her own children at heart-- look back with regret on the trivial experiments that could have been done on her but were not, and that could have improved the lot of her own present children. Speaking to herself and of herself as a child, that child-become-parent would, I judge, say: 'I would have consented because I ought to have.' Saying this, she would mean only that she was as a child a sharer in a common and social human nature, and that it was proper to take that into account in deciding what was and was not reasonable to do medically.⁴¹

More recently, David Wendler notes that "many efforts to justify nonbeneficial pediatric research attempt to sidestep Ramsey's challenge by appealing in one way or another to children's potential agency: for example, that the children would consent to it if they could, it is likely that they will retroactively 'consent' to it at some point in the future, or that reasonable individuals would give their consent." Wendler suggests that while moral agency is central to

³⁹ McCormick (1976a), op cit., p. 42.

⁴⁰ McCormick, R.A., (1976b). "Experimental Subjects- Who Should They Be? Journal of the American Medical Association 235, p. 2197

⁴¹ McCormick (1976a), op cit. p.46.

our idea of the ‘moral life,’ that children are not fully moral agents is not relevant to whether “the act of contributing to important projects has value for the contributor only to the extent that the individual autonomously decides to make the contribution... We need to accept the fact that children are not autonomous and take on directly the question of the proper treatment of individuals who are not but, if all goes well, will become autonomous adults.”⁴² For Wendler, as for McCormick, the benefits of making such a contribution will accrue to the child only after the child is no longer a child. But for Ramsey, this is the central flaw to their views. He charged that McCormick’s argument (and any subsequent arguments that call on children’s future selves), “proposes to co-opt the child in the service of obligations that hitherto have been supposed to be only electable by persons in the adult world.... Having forcibly introduced the child into the adult world, McCormick attempts to limit the damage. In effect, he bifurcates that world (for adults and children alike) into ‘what we all ought to want’ and what we ‘need not ought to want’.” Ramsey points out that if there is in fact an imperative to conduct nontherapeutic research with children, we must recognize that this imperative conflicts with the ethical principle that forbids using an individual as a research subject without his consent. He notes that while there may be situations in which moral agents must do wrong for the sake of the public good, they must acknowledge that what they are doing is wrong: “It is immoral not to do the research. It is also immoral to use children who cannot themselves consent and who ought not to be presumed to consent to research unrelated to their treatment. On this supposition research medicine ... is a realm in which men have to ‘sin bravely.’ The researcher you can trust ... is the man who does not deny the moral force of the imperative he violates.”⁴³

⁴² Wendler, D.S. (2010). The Ethics of Pediatric Research Oxford University Press: New York, p. 27.

⁴³ Ramsey (1976), op cit., p. 21.

Are researchers “brave sinners” who exploit children and other vulnerable individuals for the sake of invaluable knowledge? If the central requirement for the ethical conduct of research is the fully informed consent of a competent individual who is free to exercise his own will, then research involving an individual of any age who does not meet all prerequisites for informed consent is ethically problematic. Children are vulnerable because they lack qualities including power, intelligence, linguistic ability, and autonomy, which renders them somehow more likely to be victimized (used as a means to an end) by a research investigator. Vulnerable persons are defined by Robert Levine as those who are “relatively (or absolutely) incapable of protecting their own interests,”⁴⁴ Yet as Schneider suggests, “Who might not be vulnerable?” In addition to being vulnerable in childhood, nearly everyone will fall within that definition at some point within his or her adult lifetime.⁴⁵

⁴⁴ Levine, R. J. (1988) Ethics and Regulation of Clinical Research. Yale University Press: New Haven, CT, p. 88.

⁴⁵ Schneider, C.E., (2015), The Censor’s Hand: The Misregulation of Human Subjects Research. MIT Press: Cambridge, MA, p. 132.

3.0 WHAT IS A CHILD CAPABLE OF?

Underlying all of these commentators' arguments about whether it is ever ethical to include children in nonbeneficial research is a view of all children, including adolescents, as passive, defenseless, voiceless and opinion-less; incapable of understanding the potential risks of participation in research. It is the view held by Locke and Kant in the 18th Century, of children as "prerational and premoral," like animals or machines, whose "views can hardly be informed or trustworthy, and their responses would be either mindless compliance or irrational resistance."⁴⁶ By the time of their adolescence, however, these views about children are obviously and largely inaccurate, if they were indeed ever true. Alderson and colleagues have noted that despite the "priority it puts on respect and justice," bioethics continues to be dominated by "outdated Piagetian age-stage theories of child development that tend to emphasize children's ignorance, inexperience, and inability to make truly informed autonomous decisions, as if the mind and conscience grow as slowly as the body."⁴⁷ These authors recommend that we "do the hard work of rethinking these deeply held ideologies." Perhaps listening to youth who have actually experienced research participants could provide a necessary corrective and relevant insights into the actual vulnerabilities and concerns of children and adolescents, and dispel outdated theories of child development that emphasize

⁴⁶ Alderson, P., Sutcliffe, K. and Curtis, K. (2006). Children's competence to consent to medical treatment. The Hastings Center Report, 36 (6): 25-34, p. 25.

⁴⁷Ibid, p. 32.

children's inability to make truly informed autonomous decisions.⁴⁸

3.1 ADOLESCENT COGNITIVE CAPACITY

In his classic essay on *The Child's Right to an Open Future*, Joel Feinberg points out that there is no sharp line dividing childhood and adulthood: "they are really only useful abstractions from a continuous process of development.... In the continuous development of the relative – adult out of the relative-child there is no point before which the child himself has no part in his own shaping, and after which he is the sole responsible maker of his own character and life plan."⁴⁹ Many other commentators have noted that an individual's ability to make mature, responsible and autonomous decisions does not magically emerge on his or her eighteenth birthday;⁵⁰ moral and emotional development are gradual processes that continue from early childhood well into young 'adulthood' and beyond.

Recent advances in neuroscience and developmental psychology have found that adolescents have the mental and emotional abilities required for complex decision making,⁵¹ and many studies have demonstrated that children as young as 13 or 14 are capable of making decisions that are just as sound as decisions made by individuals aged 18 or older.⁵² As far back as 1995, the American Academy of Pediatrics Committee on Bioethics cited research that found that children achieve decisional capacity at far younger ages than previously assumed, and

⁴⁸Ibid, p. 32.

⁴⁹ Feinberg, J. (1992), *Freedom and Fulfillment: Philosophical Essays*. Princeton University Press: Princeton, NJ, p. 95.

⁵⁰ Toner, K. and Schwartz, R. L. (2003). Why a teenager over age 14 should be able to consent, rather than merely assent, to participation as a human subject of research. *The American Journal of Bioethics* 3(4), p. 38.

⁵¹ Luna B, Padmanabhan A, O'Hearn K. (2010). What has fMRI told us about the Development of Cognitive Control through Adolescence? *Brain and Cognition*, 72: 101-113.

⁵² Toner and Schwartz, op cit., p. 38.

recommended that children be involved in healthcare decisions at younger ages than are currently supported in state law.⁵³ Studies have also shown that by age 14, many children are capable of abstract reasoning. When presented with hypothetical situations that included several choices to be made that resulted in a variety of consequences, youth as young as 13 or 14 were able to consider multiple variables and combine those variables in complex and systematic ways to reach decisions that did not differ significantly from those made by older youth and young adults.⁵⁴ These findings suggest that there are no substantial differences in legal competency between “adolescents” aged 13-17 and “adults” aged 18 and older. Other research on adolescent decision-making suggests that adolescents are capable of making thoughtful and mature decisions during any number of challenging situations.⁵⁵

3.2 RECOGNIZING ADOLESCENT CAPACITIES

Hartman has written extensively on the ramifications of ignoring such findings about adolescent decision-making capacity, and has emphasized that this inattention raises “serious moral, ethical, medical, and legal concerns.” She notes: “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.” Hartman points out that in fact, “adolescents are a vital segment of the United States populace, envisaged as contributing members of a

⁵³ American Academy of Pediatrics Committee on Bioethics, (1995). Informed consent, parental permission, and assent in pediatric practice. *Pediatrics* 95:314-317, p. 316.

⁵⁴ Toner and Schwartz, op cit., p. 39.

⁵⁵ Cohn, J. M., Ginsburg, K. R., Kassam-Adams, N., and Fein, J. A. (2005). Adolescent Decisional Autonomy Regarding Participation in an Emergency Department Youth Violence Interview. *American Journal of Bioethics* 5(5): 70-74.

democratic citizenry with autonomous lives deserving of decency and dignity. As with laws tailored to the realities and needs of an aging population, one may scarcely imagine a more worthwhile populace deserving special attention than those coming of age and, thereby, fashion legal rules that do not falter when juxtaposed with factual and empirical evidence of adolescent capability.”⁵⁶

Adolescents are frequently expected to make adult decisions and take on adult responsibilities - about their own relationships or employment, for example. Youth as young as 13 or 14 are hired as babysitters responsible for caring for younger children and even infants. Youth as young as 16 are hired to be camp counselors and lifeguards and put in charge of younger children. Hartman calls attention to the irony of adults viewing adolescents as mature enough to supervise younger children during potentially dangerous situations yet not sufficiently mature to consent to their own participation in research.⁵⁷ She notes that the lack of attention paid to adolescent decisional ability and the presumption that they are not capable of making decisions shows a lack of respect for adolescents as research subjects “that seem to belie the spirit of the regulations and the historical atrocities to which the consent requirements are aimed.”⁵⁸ In real life we often treat adolescents more like adults than as children, but in the realm of research participation they are treated nearly the same way as infants and toddlers are treated: as vulnerable subjects, in need of protection because they are presumed to lack “autonomy” and the cognitive capacity required to make a decision.

Luchtenberg and colleagues provide an account of how children and adolescents view their own participation in clinical research that challenges many presumptions common to both

⁵⁶ Hartman, R. G. (2000). Adolescent autonomy: Clarifying an ageless conundrum. *Hastings Law Journal*, 51: 1266-1362, p.1266-69.

⁵⁷ *Ibid*, p. 1341.

⁵⁸ *Ibid*, p. 1337-8.

researchers and IRBs that children lack the capacity to decide about participation in research.⁵⁹ The children and youth they interviewed understood quite well that they were making a contribution to a valuable social project by their research participation. They were aware that the aim of research is to obtain knowledge to help future patients, not to provide a direct health benefit to themselves. Perhaps most significantly, youth exhibited what Luchtenberg calls a strong sense of “‘intergenerational solidarity,’... a feeling of moral duty; to acknowledge the contribution made by past generations, and a sense of owing it to future patients.”⁶⁰ These findings indicate that youth are quite capable of understanding the purpose of medical research and of making informed decisions about participation in research studies. What is more, they should be given the opportunity to make these decisions for themselves whenever possible in order to further develop their capacity for making independent decisions.

3.3 CHILD ASSENT + PARENTAL PERMISSION IS NOT SUFFICIENT

As discussed in section 2, the federal regulations governing research with children require IRBs to determine that adequate provisions “are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.” A search of IRB websites yields far more guidance about soliciting the permission of each child's parent or guardian than guidance about obtaining child assent.⁶¹ This apparent neglect of child assent may be due to a tendency to conflate consent for research with a legal contract and an inappropriate

⁵⁹ Luchtenberg, M., et al., (in press). Young people’s experiences of participation in clinical trials: Reasons for taking part. American Journal of Bioethics

⁶⁰ Ibid.

⁶¹ Whittle, A., Shah, S., Wilfond, B., Gensler, G. and Wendler, D. (2004). Institutional Review Board practices regarding assent in pediatric research. Pediatrics 113(6): 1747-1752.

emphasis on parents as the child's legally authorized representative(s). But the ethical requirement to obtain a child's agreement to participate in research should not be diluted by concepts such as "legal authorization" or "legal capacity" that imply that someone else's decision is more significant than the decision of the child. This is especially true in the case of adolescents.

In an impassioned defense of assent, William Bartholome laments that it is "a fragile idea that can easily be crushed amidst the boulders of consent, autonomy, rights, and competence."⁶² Trudy Goodenough and colleagues criticize the adult centered nature of the dual requirement for parental permission and child assent because it "frames child assent in relation to a hierarchy where legally authorized representatives are given greater powers within the consent process than the children themselves."⁶³ In cases where a child will undergo potentially painful or stressful nontherapeutic research procedures, these authors rightly question whether parents can be altruistic on behalf of a child. "The issue of child research participants is not often framed by a child centered approach. Issues of power and control are central to this debate."⁶⁴

Because the regulations require parental permission to protect children as vulnerable research subjects, a parent's decision should be based on the child's best interest. For research that offers the prospect of direct benefit, an IRB may determine that the child's assent is not required, presumably because his parents will decide whether to enroll the child for his own good. For research that offers no direct benefit and involves some degree of risk, the regulations

⁶² Bartholome, W. G., (1982). In defense of a child's right to assent. *The Hastings Center Report* 12(5): 44-45.

⁶³ Goodenough, T., Williamson, E., Kent, J. and Ashcroft, R. (2003). 'What did you think about that?' Researching children's perceptions of participation in a longitudinal genetic epidemiological study. *Children & Society* 17:113-125, p.115.

⁶⁴ Ibid, p. 115.

require “a child's affirmative agreement to participate,” but provide no guidance about situations where a parent and child disagree. Should a child’s refusal (dissent) over-ride her parent’s permission? Should a parent’s refusal to provide permission over-ride the child’s assent? Along with Denham and Nelson, I contend that a child’s agreement to participate in non-therapeutic research is ethically required in order provide her with the opportunity to “agree to be used as a means to another person’s ends.”⁶⁵ This view, however, is by no means uncontroversial.

Ross maintains that “parents alone can and must decide whether their children should participate as research subjects,”⁶⁶ and not just for potentially beneficial research. She contends that parents are entitled to compel their children to “be contributors to the moral community.”⁶⁷ But if research with human subjects is ethical only if participation is voluntary, how can it ever be ethical to include an individual who is not a willing volunteer but whose refusal is over-ruled by a parent? Ross presents a model of “constrained parental autonomy” where the source of the constraint is “respect for children’s developing personhood.” In this model, parents make decisions for their children based on their own judgment of how best to balance the child’s primary needs and the needs and interests of other family members. Ross tells us that this standard for decision-making “would limit parental discretion and would modulate the child’s role in decision-making depending on the type of decision being made, the risks involved, and the child’s own developing personhood. For example, in the research setting, particularly when the research involves risks and is not intended to benefit the child-subject, the child’s voice

⁶⁵ Denham, E. J., and Nelson, R. M., (2002). Self-determination is not an appropriate model for understanding parental permission and child assent. *Anesthesia and Analgesia* 94:1049-1051, p. 1050.

⁶⁶ Ross, L. F., (2006) Children in Medical Research: Access versus Protection. Oxford University Press: Oxford, p. 22.

⁶⁷ Ibid, footnote 93, p 22.

should be given greater weight than in the therapeutic setting.”⁶⁸ But what Ross means by giving the child’s voice “greater weight” is not at all clear.

In subsequent chapters, she remarks that it is appropriate for a parent to prohibit her child’s participation in nontherapeutic research despite the child’s desire to do so. She gives the example of a child who wants to enroll in a nontherapeutic pharmacokinetics study because it offers a \$50 payment. His parent is justified in refusing to permit his participation to protect the child from risks that the child himself is probably not aware of in his zeal to earn the \$50. Ross reminds us that parents are justified in refusing to allow their child to participate in an activity that they judge to be too risky, or not worthwhile.⁶⁹ Ross also asserts that parents should be allowed to enroll their children in minimal risk research regardless of how the child feels about it.⁷⁰ Research meeting the definition of minimal risk may involve potential discomforts that the child will be subjected to, including embarrassment talking to strangers and being in a strange setting. The child may experience participation as an inconvenience if the research visit conflicts with activities such as a basketball game or a favorite TV show. Ross maintains that “[p]arental autonomy should be respected unless their decision is disrespectful of the child’s developing personhood. Parents who value participation in social projects like advancing science may try to inculcate similar values into their child. Even if the child never shares in these goals, they are goals which responsible parents may try to inculcate.”⁷¹ Ross would probably not regard forcing one’s child to miss a favorite TV program as sufficiently “disrespectful” of the child’s developing personhood to be problematic, and concur with his parent’s decision to enroll him in the research. In this case, the parent’s decision to enroll the

⁶⁸ Ibid, p. 4.

⁶⁹ Ibid, p. 96.

⁷⁰ Ibid, p. 22.

⁷¹ Ibid, p. 22.

child over his objections does not protect the child from experiencing “risks”-- inconveniences and discomforts-- of the research, and Ross appears to be comfortable with the idea that the parent’s decision has nothing to do with protecting the child from these risks. The parent may want to encourage her child to be altruistic and to value important social projects. She may want to enroll her child because the research coordinator is a close friend and she wants to help her out, or she may be motivated by a \$50 study payment. Any of these motives appear to be sufficient for Ross, who asserts that “[t]here are morally relevant differences between competent children and adults which justify different treatment with respect to autonomy.”⁷²

Ross’s constrained parental autonomy places a child’s interests secondary to the interests of the family, with decisions made for that child based solely on the parent’s authority to decide where the family’s interests lie. This is very different from the view that parental authority exists mainly for the child’s benefit and that the primary goal of parenting is to encourage the child’s developing capacity to make his own decisions in order to bring “children to the point where they no longer require continual adult protection and supervision, and can care for themselves, at which point parental authority properly ceases.”⁷³ In this view, responsible parenting involves recognizing that as a child grows, he will spend increasingly more time beyond his parent’s reach and must learn to cope in real time with whatever life has in store.

Tamar Shapiro observed that “one of the most difficult decisions parents... have to face on a daily basis is the decision whether or not to treat a child like a child in a given situation. When is a parent justified in preventing a child from acting according to her will? When is a

⁷²Ross, L. F., (1998). Children, Families, and Health Care Decision Making. Oxford University Press: New York, NY. p. 63

⁷³ Blustein, J., Levine, C. and Neveloff Dubler, N. eds., (1999). The Adolescent Alone: Decision Making in Health Care in the United States. Cambridge University Press: New York, NY. (p.9)

child entitled to make her own choices and face the consequences?”⁷⁴ Shapiro points out that “Adult” and “Child” are status concepts; to be an “Adult” is to be “developed,” and to be a “Child” is to be “undeveloped.” But the predicament of childhood is that a child is both undeveloped and becoming developed, and because of this, adults have special obligations to protect, nurture and educate children. Schapiro notes that it is this “predicament” that provides a sound basis for an ethic of adult-child relations. She observes that the “transition from child to adult status seems... to entail some sort of bootstrapping: because she cannot avoid being a chooser, the undeveloped agent has to become herself.” It is precisely this child’s activity of “becoming” an adult that should form the basis for adults’ duties towards that child. Adults should not hinder children’s development as deliberators by forcing them to rely on adult authority in situations where they are capable of deciding for themselves; rather, they should strive to help children overcome their dependency.⁷⁵ In other words, our duty to our children is not to control them, but to encourage them to learn how to control themselves. “In order not to abuse our privilege as adults, we must make children’s dependence our enemy.”⁷⁶

Ross’s understanding of the proper relationship between parents and children is based on four very different assumptions: first, that children are members of intimate families who “make compromises for each other in order to promote the goals of the group in addition to their individual goals.” Second, she assumes that parents have the right to rear their children as they see fit, unless they abdicate from the parenting role or the state is justified in taking away their right to raise their children due to neglect or abuse. The third assumption is that becoming a parent and rearing children are important aspects of many adults’ “vision of the good life,” and

⁷⁴ Tamar Schapiro, (1999). What is a child? *Ethics* 109(4): 715-738, p 715.

⁷⁵ *Ibid*, p. 717.

⁷⁶ *Ibid*, p. 736-737.

parents have a right to obtain some degree of satisfaction from parenting and raise their children to conform to their own views of what is right and proper. Fourth, Ross assumes that children are never competent to make important decisions and should never be allowed to dissent from their parent's decisions.

Although some children have attained a threshold level of competency, I argue that competency is a necessary but not a sufficient condition to justify respect for the child's autonomy. Nevertheless, children, particularly those who have attained a threshold level of competence, should not be ignored in the decision-making process even if they should not have decision-making autonomy.⁷⁷

What Ross means by not "ignoring" a child is not at all clear. She recalls the story recounted by Gaylin of a father who compelled his son to undergo a blood draw for research even though the boy had refused when his doctor asked for his "assent." According to Gaylin, the father felt a "moral obligation" to teach his child that even if painful, some things ought to be done if it will help others. The father reportedly stated, "I was less concerned with the research involved than with the kind of boy I was raising. I'll be damned if I was going to allow my child to assume that he was entitled to be selfish and narcissistic because of some silly concept of children's rights."⁷⁸ This story outraged Bartholome, who felt the father was not teaching his son about altruism but only that might makes right and physical force prevails.⁷⁹ Ross, however, disagrees: "While empowering a child to be able to veto minimal risk research may teach the child that he has some control over his environment, it also teaches the child that strangers can restrain his parents' authority, even when it is not abusive or neglectful. It ignores

⁷⁷ Ross, (1998), op cit., p 34.

⁷⁸ Gaylin, W., (1982). The Competence of Children: No Longer All or None. The Hastings Center Report, 12 (2): 33-38, p. 37.

⁷⁹ Bartholome, (1982), op cit., p. 45.

how important it is for children to view their parents as autonomous agents.”⁸⁰ Ross does not bother to address Bartholome’s main objection to the incident. Recalling his support for allowing children to be involved in nontherapeutic research in order to encourage their moral growth, Bartholome reminds us that a child can achieve this benefit only as “a true volunteer; that he or she bring to the experience assent-- the free expression of willingness to engage in the activity.”⁸¹ In other words, a consideration of what the child is actually thinking and feeling is required. The child in Gaylin’s story complied with his father’s command simply upon “recognizing the note of authority in his father's voice.” There is no evidence that the child actually learned the lesson his father purportedly was trying to convey to him. These considerations are absent from Ross’ view.

Ross’s model of decision making for a child is not focused on the child, nor is it actually family focused; it is parent focused. In Ross’s model, asking the child to assent to his parent’s decisions may be a nice touch, but not ethically necessary. Indeed, Ross contends that requiring that investigators seek assent may actually be unethical by being disrespectful of parental authority. She asserts that to set the focus of decision-making on a child’s best interest “does not give enough weight to the child’s family with whom his interests are inextricably bound.”⁸² But the interests of the family are not central in Ross’s model; parents’ singular authority to decide what the interests of the family are central. She stresses that parental authority is not solely duty-based, but is justified on the grounds that parents have a right “to raise their children according to the parents’ own standards and values and to seek to transmit those standards and values to their children....Thus, requiring parental permission not only serves to promote the

⁸⁰ Ross, (2006) op cit., p. 97.

⁸¹ Bartholome, (1982), op cit., p. 44.

⁸² Ross, (2006) op cit., p 89.

child's best interest but also serves to respect a legitimate parental interest in making decisions for their child."⁸³

Ross admits that adults may not always be right: "The presumption of adult competency is over inclusive." Citing Appelbaum, Lidz, and Meisel, Ross notes that the data is inconclusive "to test whether consent given by adults is significantly different (presumably better) than consent given by competent children."⁸⁴ Still, she maintains that "even if a child is competent, there are advantages in treating her differently from an adult, particularly with regard to respect for her autonomy." She claims that limiting a "child's short-term freedom" serves to promote the child's long-term autonomy, while "respect for a threshold of competency in children places the emphasis on short-term autonomy rather than on a child's lifetime autonomy. Children need a protected period in which to develop 'enabling virtues' (habits, including the habit of self-control), which advance their lifetime autonomy and opportunities." Purportedly, to allow children this protected time to mature and develop, parents are to decide everything for the child. It remains to be seen how relying exclusively on parents for decisions will affect a child's ability to develop these vital "enabling virtues," including, one supposes, the ability to make competent and informed decisions.

Ross's view of parental autonomy brings to mind the phenomenon of "helicopter parenting," a pejorative expression that refers to parents who pay extremely close attention to their child's experiences and problems. "Helicopter parents are so named because, like helicopters, they hover overhead."⁸⁵ Segrin and colleagues refer to this as "overparenting...marked by the application of developmentally inappropriate levels of control

⁸⁴Ross (1998), op cit., p. 57-58.

⁸⁴ Ibid., p. 59.

⁸⁵ http://en.wikipedia.org/wiki/Helicopter_parent

and tangible assistance to late adolescents and emerging adults.” These authors found evidence that this form of parenting is “not associated with adaptive outcomes for young adults and may indeed be linked with traits that could hinder the child’s success.”⁸⁶ Young adults whose parents were described as “helicopter parents” did not develop the same level of coping skills as those with parents who allowed them to resolve challenges on his or her own. Effective coping and problem solving skills are only acquired through experience. Overparenting limits a child’s opportunity to practice effective problem-focused coping skills, because “parents frequently step in to solve the child’s problems for him or her, and in some cases, act to prevent certain problems from emerging in the first place.”⁸⁷

It is a parent’s responsibility to decide which decisions to make alone, which decisions should be shared with the child, and which should be left to the child himself. Providing encouragement and support for a child’s developing capacity to make decisions is central to a model of parental authority based on both the child’s and the parent’s best interests – their mutual interest in the child becoming a responsible and competent adult. Ross’ model of parental autonomy for decisions made for children does not appear to be at all respectful of child development that should rightly include the opportunity to learn how to make important decisions by being allowed to make those decisions without parental permission.

The decision to participate in a minimal risk behavioral research study is exactly the kind of decision that adolescents should be allowed to make without parental permission. As Paul Baines and others have pointed out, the concept of assent is ill thought-out and not clearly defined, and as a result, it is often misunderstood and misapplied by IRBs. “Research may allow

⁸⁶ Segrin, C., Woszidlo, A., Givertz, M., and Montgomery, N. (2013) Parent and child traits associated with overparenting. *Journal of Social and Clinical Psychology*, 32: 6: 569-595, p. 570.

⁸⁷ Ibid, p. 575.

competent children to assent, while asking their parents to consent. The harm here is that if children are competent, their decisions should be respected: they should consent. Assent may mean that the researcher does not consider whether the children should themselves consent and so may fail to respect the autonomy of a competent child.⁸⁸

⁸⁸Baines, P. (2011). Assent for children's participation in research is incoherent and wrong. Archives of the Diseases of Childhood, 96: 960-962, p. 961-2.

4.0 RESPECT FOR ADOLESCENTS IN RESEARCH

The National Commission Report and Recommendations on Research Involving Children (1977) begins with an affirmation of the importance of observational research with children, “for the health and well-being of all children,” and stresses that research about health conditions and risk behaviors that affect adolescents is essential to understanding the “special needs of adolescents.”⁸⁹ The significant morbidity and mortality caused by negative health behaviors that often begin in adolescence, such as unprotected sexual activity and substance use, underscores the need for wide ranging observational research on the developmental and behavioral origins of adolescent risk taking behaviors. Youth advocates have long urged that “every opportunity be seized to learn what programs are effective in adolescent risk reduction and health maintenance. Given the projected costs of current adolescent morbidity in fiscal and human terms, public accountability requires that every dollar be spent as effectively as possible and that the false security of futile efforts be rigorously avoided.”⁹⁰

The larger adolescent population fails to benefit maximally from research when some potential participants are systematically excluded from participation, because the validity and generalizability of results are compromised. Such research may also be unethical *because* it is

⁸⁹ U.S.Department of Health and Human Services (1977) National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Research involving children: Report and recommendations.

⁹⁰ Smith Rogers, A., D’Angelo, L. and Futterman, D. (1994). Guidelines for adolescent participation in research: Current realities and possible resolutions. IRB: A Review of Human Subject Research 16(4): 1-5.

ineffective. Emanuel, Wendler and Grady point out that the overarching goal of research is to contribute to generalizable knowledge in order to improve human health. Using human research subjects to further this goal requires ethical considerations to ensure that those subjects are treated with respect. These authors propose seven universally applicable requirements to provide a framework for determining whether human subjects' research is ethical. The research must be valuable; it must use scarce resources to increase our knowledge about an important health issue. The research must also be methodologically rigorous, and subject selection must be fair and aligned to the scientific objectives and not be exploitative or based on mere convenience.⁹¹

To be effective and of value, research regarding adolescents' behaviors and attitudes must include broad and representative samples of adolescents, including those who cannot or will not go to a parent for permission to participate in the research. The exclusion of these vulnerable youth from participation and thus the applicability of the findings of research is a violation of the Belmont principle of justice and the ethical requirements discussed by Emanuel and colleagues. It is both unfair and contrary to the well-being of this population of vulnerable youth if findings from research that does not include the experiences of these youth lead to interventions that turn out to be inappropriate and ineffective for them. If the research itself affords any benefit, it is unfair to exclude members of this population from participating.

In an ideal world, every adolescent would have at least one supportive parent available to provide guidance when faced with an important decision. But in the real world, in the United States, an estimated 1.5 million adolescents are runaways or otherwise living on their own

⁹¹ Emanuel, E.J., Wendler, D., and Grady, C., (2000). What makes clinical research ethical? Journal of the American Medical Association, 283(20): 2701-2711.

without any kind of parental support.⁹² Many other adolescents have a supportive parent but are unwilling to accept that support, for any number of reasons that have to do with the normal processes of growing up. Requiring parental permission for adolescents to participate in observational research about behaviors that affect their health limits participation to those adolescents who have a parent available and willing to provide permission.⁹³

In a review of school-based observational research studies, Chartier and colleagues found that requiring parental permission not only lowered student participation rates overall but resulted in the exclusion of specific demographic (minority) and high-risk groups. For example, in a trial of a gang prevention program that recruited youth from 18 schools across the US, at schools that required “active parental permission” (e.g., signed parental permission forms), student participation was affected with respect to race, parental education, family structure, and parental level of involvement with their child at school. These authors concluded that the requirement for parental permission “led to systematic exclusion of students at risk for disruptive behavior problems from programs that target these conditions.”⁹⁴

Excluded adolescents include those whose parents are unavailable or unwilling to care for them, those who have been placed in foster care or other court mandated placements, those who have run away from home because of abuse or neglect, and those who live with an adult who is not their parent due to any number of family circumstances. Other adolescents may be barred from participating because they are not willing to approach a parent out of fears that the research topic will raise questions about their behavior and foment trouble at home. Since youth

⁹² Blustein J, Levine C, Dubler NN, (1999), eds. The Adolescent Alone: Decision-Making in Health Care in the United States. Cambridge: Cambridge University Press, p. 3.

⁹³ Olds, R.S., (2003). Informed consent issues with adolescent health behavior research. American Journal of Health Behavior 23(s3):s248-s263.

⁹⁴ Chartier, M., et al., (2008). Passive versus active parental permission: implications for the ability of school-based depression screening to reach youth at risk. Journal of School Health 78(3): 157-164, p. 158.

who find themselves in these circumstances are also likely to have experienced significant stressors such as neglect, physical or sexual abuse or parental substance abuse or criminal activity, adolescents excluded for any of these reasons may be most at risk for the kinds of behaviors that adversely affect their health and wellbeing. The requirement for parental permission effectively bars their participation and it also undermines the validity of research on the causes and prevalence of these behaviors. The effectiveness of any interventions based on such research would be highly suspect, especially for these most vulnerable youth.

4.1 ADOLESCENTS' WELL-BEING, OVER-PROTECTION AND AUTONOMY

As discussed in section 3.2 above, outside of the research context we often treat adolescents more like adults than as children. But in the realm of research participation they are treated nearly the same way as infants and toddlers are treated: as vulnerable subjects, in need of protection because they are presumed to lack “autonomy” and the cognitive capacity required to make a decision. We generally treat someone as an adult when we have reason to believe that individual has the capacity to be held responsible for her own actions. In general, we don't hold children responsible for their actions to the same extent that we hold adults responsible. But under certain circumstances we do hold them responsible, as in the case of a 14 year old tried as an adult in criminal court. In real life we often treat adolescents more like adults than as children, but in the realm of research participation it is “one size fits all,” with adolescents treated in much the same way as infants and toddlers: as vulnerable subjects in need of protection.

During adolescence, individuals' opportunities to make increasingly complex and important choices are expanding, and many of these choices will affect their current and future health and wellbeing. On any given day, an adolescent may decide to have sex without using effective birth control, experiment with an illicit drug, drink alcohol or smoke a cigarette. That same adolescent may also decide to apply for a job, practice her violin, study for an important exam rather than attend a party with friends, apply to a college or university, or volunteer to help others in his community. The expansion of the range and scope of decision-making is part of the process of healthy development for this age group, a process that involves "learning how to make informed decisions, manage risks and negotiate options."⁹⁵ Research aimed at finding effective strategies to support adolescents' making healthy and appropriate choices is critical, but researchers may hesitate to include adolescents in their research because of hurdles posed by IRB review, and adolescents may not be willing to participate in research when parental permission is required.

The permission of a parent or legal guardian for a child's participation in research is supposed to provide that child with additional protections from the potential risks of research participation, so the requirement for parental permission should also be based on the nature of the research and an assessment of the risks and potential benefits of participation, as well as the individual circumstances and capacity for "self-determination" of the children who are to be included in the research. When considering whether to require parental permission for behavioral or observational research, the relevant question for Institutional Review Boards (IRBs) to consider is whether parental permission is an appropriate protection for an adolescent to participate in a particular research protocol. IRBs are charged with determining the nature of

⁹⁵ Flicker, S., and Guta, A. (2008). Ethical approaches to adolescent participation in sexual health research. *Journal of Adolescent Health* 42:3-10, p. 3.

the risks posed by the research, and this determination should be accompanied by an assessment of whether parental permission may be required to protect adolescents from research risks that the adolescents themselves may not be sufficiently mature to understand. This assessment may require that IRB members consider the possible repercussions of research participation to adolescents in the future. For example, research that includes the banking of biological specimens for genetic analysis may pose risks that even mature adolescents are not capable of fully understanding if genetic information will be returned to subjects. Other research may pose a risk to an adolescent's future, perhaps limiting opportunities for educational or other benefits if research participation or results are revealed. Research that involves non-invasive Magnetic Resonance Imaging (MRI) may appear to an adolescent to pose only the risk of boredom, but if the MRI reveals an abnormality that requires clinical care, a parent will be financially obligated for this follow-up care.

In contrast, for adolescent participation in behavioral or observational research that involves questions about behaviors that impact adolescent health and well-being, IRBs should be suggesting more appropriate protections that are tailored to the minimal risks posed by the research and the actual vulnerabilities of adolescents. An age-appropriate consent process, for example, would be an appropriate protection if it involved carefully constructed materials that use simple and direct language and ample opportunities for discussions that allow both the adolescent and the researcher to determine whether the potential risks of participation are adequately understood. Another appropriate protection might be to provide adolescents with a list of community resources that provide confidential services to teens who are experiencing physical or emotional problems that are the focus of research. Investigators should also be prepared to provide referrals to social, psychological, or educational services or resources if

they identify an adolescent at risk of serious harm, or if the adolescent were to request such a referral.

When considering low-risk, observational research about adolescents' experiences of life events, including negative experiences such as abuse, drug or alcohol misuse or unhealthy sexual practices, IRB members tend to overstate the potential risks of asking questions about these experiences, possibly imagining that the questions could elicit feelings of shame, guilt and embarrassment that could lead to a serious episode of depression and even trigger a suicide attempt.⁹⁶ Despite evidence to the contrary, there are also concerns that simply by asking an adolescent to answer questions about sexual activity, drug or alcohol use, or delinquent behaviors will encourage him or her to engage in these behaviors.⁹⁷ Carl Schneider's scathing critique of IRBs includes the charge that the paternalism inherent in the current regulatory system "injures those it purports to protect.... IRBs impede research with the sexually abused, minority groups, and the mortally ill. Are they protected, or silenced? Protected, or patronized? Protected, or obscured from public awareness and responsibilities?"⁹⁸ He cites professionals, including therapists and social workers who have worked with abused or marginalized individuals including the mentally ill or those with substance abuse problems, who suggest that IRB members, like the rest of society, would rather not deal with these uncomfortable issues. He notes that those who have not suffered from abuse, as most IRB members are likely not to have suffered, are more likely to object to questions about abuse than those who have actually experienced it. Adolescents who are seriously ill, or abused, or are members of a sexual minority are even more likely to be over-protected by IRBs, and effectively silenced as a result.

⁹⁶ Schneider, C.E., (2015), op cit., p. 19.

⁹⁷ Collogan, L. K., and Fleischman, A. R., (2005). Adolescent research and parental permission. In Eric Kodish, ed. Ethics and Research with Children: A Case-Based Approach. Oxford University Press: Cary, NC.

⁹⁸ Schneider, op cit., p. 133.

There is also evidence to suggest that investigators are hesitant to include adolescents in observational research about topics such as sexual health behaviors because of concerns about having to navigate IRB review and the assumption that they will be required to obtain parental permission. Sexuality and healthy sexual behavior are frequently difficult topics for parents to discuss with their children, and public debate continues over the appropriateness of formal and informal sex education for children and teens. IRBs may be so risk-averse because of concerns about possible negative parental reactions that they refuse to approve a waiver of parental permission for important research that is then rendered impossible to conduct by the requirement to obtain parental permission for each participating youth. “Consequently, young people are often excluded from participating in research and initiatives that may serve to improve their health.”⁹⁹

4.2 POTENTIAL BENEFITS FROM RESEARCH PARTICIPATION

When IRBs use a “one size fits all” standard for reviewing all research involving individuals under the legal age of majority, the requirement for parental permission does not serve to protect individuals and may create situations where adolescents are barred from participating in research that could benefit all adolescents in the future. But there may also be potential benefits to adolescents from being asked to share their stories with research investigators. Marginalized youth, including those who identify as lesbian, bi-sexual, gay or transgendered (LBGT), or have

⁹⁹Flicker, S. and Guta, A. (2008), op cit., p. 8.

mental health problems, drug addiction or other stigmatizing conditions, may gain a measure of self-respect from being asked to contribute their personal experiences to help other youth in the future. Participation in research that has been carefully constructed to provide appropriate protections may also provide adolescents with tangible benefits, including gaining a sense of self-awareness and an opportunity to obtain guidance and support from adult professionals who are sympathetic, nonjudgmental, and experienced with adolescents' problems and behaviors.

Ott and colleagues¹⁰⁰ surveyed parents of adolescents who participated in a longitudinal study of sexually transmitted infections (STIs) about the reasons they permitted their child to participate. Parents frequently cited their child's own eagerness to participate as the most important reason they gave their own permission, but also cited "contact" and "other developmental benefits" they believed their children would receive. Some felt that the study would give their adolescent the opportunity to have someone to "talk to" or to "talk openly" about personal matters. This perception that research participation is beneficial because it offers their child an opportunity to connect with a caring, professional adult who may be able to provide sound information or advice to their child is significant. "For a family living in a resource-poor community, such as those participating in this study, research participation may be one of only a few opportunities for adolescents to have ongoing contact with an engaged professional adult. It raises the issue of developmental benefits, or whether there are benefits that are specific to a particular age or developmental stage. In this case, if research meets

¹⁰⁰ Ott, M. A., Rosenberger, J. G., and Fortenberry, J. D., (2010). Parental Permission and Perceived Research Benefits in Adolescent STI Research. Journal of Empirical Research on Human Research Ethics, 5(2): 57–64, p. 60.

adolescents' developmental needs for adult connection, mentors, and role models, this could be considered a developmental benefit.”¹⁰¹

It is critical that such research with adolescents be conducted by investigators who are experienced and knowledgeable about adolescents' strengths and vulnerabilities. Such research should also be carefully tailored to provide ample opportunities for subjects to learn about themselves and about the consequences of their health behaviors. Participants should also be kept informed about the research results whenever possible, in order to enhance their own knowledge about science and to evidence continued respect for their contribution to the research enterprise. There must also be safety protocols in place to provide care for adolescents who reveal self-harming behaviors, or who identify themselves as being in a crisis situation. These protocols could be as basic as having a list of community resources available to all adolescents who complete an anonymous survey, or as complex as having a written procedure for contacting a licensed clinician and escorting a youth who has endorsed suicidal intent to the nearest emergency room for psychiatric assessment.

4.3 CONCLUSION: CONSENT AS A COMPONENT OF ETHICAL RESEARCH WITH ADOLESCENTS

The ethical conduct of research with children should not be based on a “one size fits all” approach that fails to recognize the variation in developmental stage of children and ignores the differences among the types of risks posed by research participation. To conduct research

¹⁰¹ Ibid, p. 61.

with adolescents in an ethical manner, IRBs and research investigators should consider the individual capacities of the adolescents who will be asked to participate and the actual risks that are posed by research participation. Parental permission should not be presumed to be an appropriate or effective protection for adolescents if they themselves are able to comprehend and assess the potential risks of research participation. When risks are limited to those that present the adolescent with inconvenience, minor discomfort or possible loss of privacy, he should be asked to provide direct consent to research participation. The requirement for parental permission is currently applied to all research with adolescents without regard for their emerging capacity to make decisions for themselves. This is disrespectful of adolescents. As Frader comments, “It seems time to concentrate more on developing valid and reliable methods to assess the capacity of individual children to decide about participating in [non-beneficial research], rather than working to impose inflexible procedural rules.”¹⁰² Inflexible application of the requirement for parental permission also limits participation to adolescents who have a parent willing and available to provide permission, and effectively bars the participation of youth whose voices deserve to be heard: adolescents who for any number of reasons are estranged from their parents.

The account presented by Luchtenberg and colleagues helps underscore the extent to which youth and young adults can articulate understanding of and insight into the research process. The youth they interviewed described gaining a sense of empowerment from better understanding their condition and helping others; intangible benefits that IRBs fail to recognize.¹⁰³ Perhaps including youth representatives who have actual experience as research

¹⁰² Frader, J. E., (2003). We need substantive criteria for decisions by children. (2003) The American Journal of Bioethics, 3 (4): 8-9.

¹⁰³ Luchtenberg, (in press), op cit.

participants could provide IRBs with refreshing and relevant insights into the actual vulnerabilities and concerns of children and adolescents. Carter and others have recommended the establishment of child-led research review committees to assist adults in their understanding of what is really important to children. Carter notes that we need “to acknowledge that children are the experts in the day-to-day spaces of childhood.”¹⁰⁴ Researchers and IRB reviewers may lack the expertise and understanding of the actual concerns of adolescents. For the future of research it is crucial to incorporate the youth voice throughout the research process.

There are at least 1.5 million adolescents in the United States who live on their own with no family support.¹⁰⁵ Millions of other children and teens are in foster care or have been adjudicated dependent or delinquent and are considered to be wards of the state; not in the custody of parents. There are also untold numbers of children and adolescents who live with grandparents, aunts or adult siblings, who have little or no contact with their biological parents. All of these children should be represented in research on adolescent health behaviors; in fact, it is especially important that the stories of these children be heard in order to begin to explain and mitigate health behaviors that put adolescents at risk.

¹⁰⁴ Carter, B. (2009). Tick box for child? The ethical positioning of children as vulnerable, researchers as barbarians and reviewers as overly cautious. International Journal of Nursing Studies, 46: 858-864 p. 859.

¹⁰⁵ Blustein & Dubler NN, (1999), op cit., p. 3.

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