The Limits of Autonomy: The Belmont Report and the History of Childhood

TAMAR W. CARROLL* AND MYRON P. GUTMANN**

*Department of History, Cornell University, 450 McGraw Hall, Ithaca, New York 14853.
Email: twc57@cornell.edu.

**Inter-university Consortium for Political and Social Research, Population Studies Center, Department of History, School of Information, University of Michigan, PO Box 1248, Ann Arbor, Michigan 48106. Email: gutmann@umich.edu.

ABSTRACT. This article examines the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research recommendations on children as research subjects in the context of the history of American childhood. The Commission's deliberations took place during the post-World War II period of rapid changes in understandings of childhood and adolescence, brought on in part by school children's highly visible roles as risk-taking protagonists in the polio vaccine trials and the civil rights movement; by the children's rights movement and court decisions granting children and adolescents greater autonomy in divorce cases and in delinquency and mental health hearings, among other rights; and finally by a renewed movement for child protection led by parents of disabled children and by polio survivors themselves. The National Commission's final recommendations emphasized the need for parents to approve, for children above age seven to assent to research, and for children in special care (either medical, psychiatric, or because they were orphans or had committed juvenile crimes) generally to be subjects of research only if there was some direct connection between the reasons for their special care and the objectives of the research. Ultimately, in these recommendations, the National Commission charted a middle ground between the children's rights movement, which advocated enhanced self-determination for children, and the disability rights movement, which urged greater protection for children. **KEYWORDS:** National Commission for the Protection of Human Subjects of

Biomedical and Behavioral Research, children as research subjects, autonomy, informed consent, research ethics, civic childhood.

IN 1975–76 in Bethesda, Maryland, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrestled with the concept of autonomy as it applied to the ethics of children’s participation in research projects. Spurred directly by inflammatory news in the early 1970s about dangerous biomedical experiments on children and adults (most visibly the federally funded Tuskegee syphilis experiments), the Commission’s deliberations coincided with broader societal discussions.¹ The eleven-member Commission, composed of research scientists, doctors, philosophers, and lawyers, as well as a civil rights activist, was not alone in its attempt to evaluate the moral and legal meanings of childhood and the age of consent in American society in the 1970s. The Commission’s deliberations took place during the post-World War II period of rapid changes in understandings of childhood and adolescence, brought on in part by school children’s highly visible roles as risk-taking protagonists in the polio vaccine trials and the civil rights movement; by the children’s rights movement and court decisions granting children and adolescents greater autonomy in divorce cases and in delinquency and mental health hearings, among other rights; and finally by a renewed movement for child protection led by parents of disabled children and by polio survivors themselves.²

1. The authors explore reports of both unethical biomedical and behavioral research in the United States during the post-World War II period, in “Why Didn’t the Belmont Report Talk about Disclosure?” unpublished manuscript in authors’ possession. For the earlier history of research on children, see Alice Boardman Smuts, *Science in the Service of Children, 1893–1935* (New Haven: Yale University Press, 2006). For the history of the Tuskegee syphilis experiments, see especially James H. Jones, *Bad Blood: The Tuskegee Syphilis Experiment*, rev. ed. (New York: The Free Press, 1993); Susan M. Reverby, ed., *Tuskegee’s Truths: Rethinking the Tuskegee Syphilis Study* (Chapel Hill: University of North Carolina Press, 2000); Amy L. Fairchild and Ronald Bayer, “Uses and Abuses of Tuskegee,” in *Tuskegee’s Truths: Rethinking the Tuskegee Syphilis Study*, ed. Susan M. Reverby (Chapel Hill: University of North Carolina Press, 2000), 598–604.

2. In 1975, e.g., the U.S. District Court in Philadelphia ruled that a child whose parents wanted to involuntarily commit him or her to a mental institution had “the right to counsel, a hearing and other safeguards when they oppose the commitment.” “Mental Health,” *Washington Post*, 23 March 1976, A9; See also Box 7, Mtg. 17, Tab 20, U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral

Established in 1974 by Title II of the National Research Act (P.L. 93-348), the Commission was charged by Congress with formulating ethical guidelines for the treatment of human subjects. Any researcher receiving Department of Health, Education and Welfare funds and experimenting on human subjects was mandated to comply with these guidelines, which created the Institutional Review Board (IRB) system and a set of regulations. While the Commission heard testimony on a wide range of controversial research practices, its *Research Involving Children* report generated the most internal disagreement, prompting two formal dissents from the Commission's official recommendations. The guidelines for research on children, as we will see, were proposed in 1977, and emphasized the need for parents to approve, for children above age seven to assent to research, and for children in special care (either medical, psychiatric, or because they were orphans or had committed juvenile crimes) generally to be subjects of research only if there was some direct connection between the reasons for their special care and the objectives of the research.

The Commission's work was capped by the *Belmont Report* (1978), entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," which has since set the standard for ethical considerations related to research on human subjects. The Belmont Report, the general recommendations of the Commission, and the specific recommendations about research involving children have been largely sustained for the past thirty years, and they now apply to the biomedical, behavioral, and social sciences, not only for all federally funded research, but by extension, virtually all academic and much other research conducted in the United States. The Commission's work has not always been applauded, but it has made a systematic contribution to how scientific research has been conducted in the United States.

Research Collection, National Reference Center for Bioethics Literature of the Kennedy Institute of Ethics, Georgetown University, Washington, DC (hereafter NCPHSBB), and U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research Involving Children: Report and Recommendations* (Washington, DC: Department of Health, Education and Welfare, 1977). For children's and adolescents' legal status, see Andrew Jay Kleinfeld, "The Balance of Power among Infants, Their Parents and the State," *Family Law Q.*, 1970, 4, 319-50. (This is part 1 of a three-part essay. The other two parts are published in *Family Law Q.* 4 and 5, December 1970 and 1971.)

If the impact of the Commission's work has been vast, its history is not especially well known, and the process by which it reached its recommendations about children and research has been relatively little studied.³ This article is an effort to write that history, both for its intrinsic interest as a topic in the history of research and research ethics, and because that history took place in a context that is important to understand. The National Commission's discussion of research on children took place in an era when attitudes about children and adolescents were changing, and when notable transformations in how young people were treated came about as a result. In addition to telling the story about the National Commission's recommendations about research on children, we also attempt to put those discussions and recommendations in the context of the history of childhood and the family in the United States in the 1960s and 1970s.

All this debate took place in another context, this one a scholarly discussion of what was then a newly discovered history of childhood that was reformulating notions of childhood and children's autonomy vis-à-vis parents and the state. During one of the Commission's meetings, biomedical ethicist Albert Jonsen cautioned his fellow members, noting that:

One of the most important things that we have to do as we proceed in these studies is to begin to consider the nature of the child as a moral being, as a person as it were. It seems to me it is a very peculiar thing that in our culture really very little explicit attention is paid to the ethics of dealing with children. We live with the kind of an ethical tradition where discussions of ethics always presume that the other is an autonomous being capable of responding with freedom and intelligence to actions made toward them, and therefore the child is a kind of an ethical anomaly in our culture. . . . Is the child an autonomous being? Are our obligations toward the child primarily protective or primarily fostering and do children have moral obligations . . . ?⁴

3. A helpful overview of research on children, as well as an introduction to the work of the National Commission on research on children, is provided by Michael A. Grodin and Leonard H. Glantz, eds., *Children as Research Subjects: Science, Ethics, and Law* (New York: Oxford University Press, 1994).

4. Transcript of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 20th Meeting, 9–10 July 1976, Bethesda, Maryland, 296, available in NCPHSBB.

After laying out these key questions facing the Commission, Jonsen wondered whether “a little history” could give the Commissioners “some perspective” on these ethical quandaries, and recommended they read “a remarkable book,” Philippe Ariès’ *Centuries of Childhood*.⁵

Translated from its original French in 1962, *Centuries of Childhood* quickly entered English-language scholarship and helped to constitute a new field of study, the history of the family.⁶ Ariès tracked the use of language in formal and informal writings as well as images of children in paintings and books and demographic information to formulate his novel thesis. Childhood, Ariès argued, was a social construct and a recent one at that—there was simply “no place” for childhood in the medieval world, where children were treated like and acted as little adults. It was only in the seventeenth century, for members of the nobility and bourgeois, and the nineteenth century, for the working class, he posited that the idea of a separate stage of life known as childhood and associated with innocence gained prevalence. This was, for Ariès, not necessarily a good thing, as children were increasingly isolated within the nuclear family.⁷

While subsequent historians have disputed Ariès’ findings, stressing the continuity in treatment of children and ideas about childhood rather than a radical break occurring with the onset of the early modern era, his work has continued to be the starting point for debate about the historical and contemporary meanings of childhood within broad contexts.⁸ For the National Commission, struggling to determine how much say children should have over

5. Ibid., 322. Philippe Ariès, *Centuries of Childhood*, trans. Robert Baldick (London: Jonathan Cape, 1962).

6. Nara Milanich, “Whither Family History? A Road Map from Latin America,” *Am. Hist. Rev.*, 2007, 2, 439–58.

7. Ariès, *Centuries of Childhood*, especially 33.

8. See especially David Kertzer and Marzio Barbagnoli, eds., *The History of the European Family*, 3 vols. (New Haven, Connecticut: Yale University Press, 2001–03); Patrick H. Hutton, *Philippe Ariès and the Politics of French Cultural History* (Amherst: University of Massachusetts Press, 2004), 92–112; Lawrence Stone, *The Family, Sex and Marriage in England, 1500–1800* (New York: Harper and Row, 1977); and Linda A. Pollock, *Forgotten Children: Parent–Child Relations from 1500 to 1900* (New York: Cambridge University Press, 1983). For a recent popular discussion of *Centuries of Childhood*, see Joan Acocella, “Little People: When Did We Start Treating Children like Children?” *New Yorker*, 18 August 2003, 138, at http://www.newyorker.com/archive/2003/08/18/030818crbo_books (accessed 9 March 2010).

their participation in research, Ariès presented an interesting dilemma: Were childhood and adolescence distinct developmental stages in life? If so, to what degree should children be treated autonomously like little adults—with the right to refuse or chose to participate in experiments? As a more recent historian of the family, Elliot West, posed, “If the family is, among many things, a relationship of power, where should a parent’s authority stop and a child’s begin?”⁹ Could parents ethically override their children’s wishes to participate in experiments?

NATIONAL COMMISSION PUBLIC HEARING

In the 1960s and early 1970s, a series of important publications on medical ethics had raised questions about the conduct of research on children. Most notably, Dr. Henry Beecher’s influential 1966 review of medical research practices in the United States featured four examples of unethical research on children, including an experiment that exposed newborns to x-rays; the testing of an acne drug on institutionalized children and youth, even after evidence of liver damage to the subjects; and the unnecessary use of thymectomy and skin grafts on children undergoing heart surgery.¹⁰ Eight years later, as the Commissioners began their deliberations, the ethics of children’s participation in research remained murky. Dr. Hellegers of Georgetown’s Kennedy Institute noted that the Nuremberg Code, formulated in the aftermath of Nazi atrocities, required consent from all research subjects: “The voluntary consent of the human subject is absolutely essential. This means that the person should have legal capacity to give consent.”

9. Elliot West, *Growing up in Twentieth-Century America: A History and Reference Guide* (Westport, Connecticut: Greenwood Press, 1996), 238.

10. The fourth example, the Willowbrook hepatitis study, is discussed in greater detail later. Henry K. Beecher, “Ethics and Clinical Research,” *N. Engl. J. Med.*, 1966, 274, 1354–60. The significance of Beecher’s article is discussed by Jon Harkness, Susan Lederer, and Daniel Wikler, in “Laying Ethical Foundations for Clinical Research,” *Bull. World Health Org.*, 2001, 4, 365–72, which includes a reprint of the original article and is available online at <http://www.who.int/docstore/bulletin/pdf/2001/issue4/vol79.no.4.365-372.pdf> (accessed 9 March 2010). Also important in raising awareness of unethical research practices on both adults and children was Maurice Pappworth, *Human Guinea Pigs: Experimentation on Man* (London: Routledge and Kegan Paul, 1967). For the influence of Beecher and the development of subsequent regulations governing research on children, see also Lainie Friedman Ross, *Children in Medical Research* (New York: Oxford University Press, 2006).

If one interpreted the Nuremburg Code strictly, Hellegers posited, “that eliminates children and the incompetent from medical research.”¹¹ The eminent ethicist Paul Ramsey did just that, arguing that parents could only consent to their child taking part in research that would be directly beneficial to the child. Medical ethics were clear, Ramsey stated, “when there is no possible relation to the child’s recovery, a child is not to be made a mere object in medical experimentation for the sake of good to come.” Furthermore, Ramsey contended, any attempt to seek the consent of children for their participation in research “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.”¹²

In contrast to Ramsey, from the start of their lengthy deliberations, the National Commission formulated a pro-research position and sought to justify experimentation on children to the public while also meeting Congress’ mandate for ethical and legal regulations—limits—on investigators. The Commissioners’ backgrounds—two biomedical researchers, three physicians (with university appointments), three lawyers (two of whom were professors of law), two ethicists, and a civil rights leader—inclined them toward a generally positive view of scientific and medical research.¹³ Chairman

11. For the text of the Nuremburg Code, see <http://ohsr.od.nih.gov/guidelines/nuremberg.html> (accessed 9 March 2010). See also, Dr. Hellegers, “Consent for Incompetent Risky,” *Family Practice News*, 15 May 1976, Box 8, Mtg. 18, Tab 13, NCPHSBB.

12. Paul Ramsey, *The Patient as Person: Explorations in Medical Ethics* (New Haven: Yale University Press, 1970), 11–19, esp. 12, 14.

13. Title II of the National Research Act, entitled “Protection of Human Subjects of Biomedical and Behavioral Research,” established an eleven-member National Commission. Congress directed the HEW Secretary to appoint five Commissioners who were or had been engaged in research involving human subjects, and six others who had never engaged in research with human subjects. The Commissioners were to be “individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government and public affairs.” *National Research Act P.L. 93–348*. The DHEW Secretary’s staff, including Charles Lowe, Duane Alexander, and Barbara Mishkin, helped to select the Commissioners, culling from a list of hundreds of CVs submitted by Senator Kennedy’s staff. According to Charles McCarthy, NIH liaison to the Commission, the Commissioners gained eminence after the publication of the Belmont Report; while certainly accomplished at the time of their appointment, with several exceptions, they were not “nationally known” at that time. McCarthy explained that “People thought, oh, ho-hum, they’re just a bunch of also-ran writers and teachers from around the country, and it was not thought to be a blue ribbon commission at the time. Now, when people

Kenneth Ryan, a Harvard obstetrician and Chief of Staff for the Boston Hospital for Women, thus summarized the task before the Commission: "We all know that research can be a powerful force for good, for improved patient care and well being, if it is well applied. And, that is our job, to make sure, as we go down the line, that it is well applied and regulated." In particular, Ryan and Commissioner and pediatric researcher Robert E. Cooke stressed that children's physiology is different from adults', and that in order to find out the

look back, of course, they think it was the best commission ever put together. But that is hindsight. Prospectively, it was not. It was thought to be a weak commission." Charles R. McCarthy, interviewed by Patricia C. El-Hinnawy, 22 July 2005, Bethesda, Maryland, Belmont Oral History Project, available at <http://www.hhs.gov/ohrp/belmontArchive.html#histArchive2> (accessed 9 March 2010). The members of the Commission, listed with their affiliation at the time, were: Kenneth John Ryan, M.D., Chief of Staff, Boston Hospital for Women; Joseph V. Brady, Ph.D., Professor of Behavioral Biology at Johns Hopkins University; Robert E. Cooke, M.D., President, Medical College of Pennsylvania; Dorothy I. Height, President, National Council of Negro Women, Inc. (Height was a life-long civil rights and women's rights activist, she also held an M.A. in Educational Psychology); Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at San Francisco; Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center; Karen Lebacqz, Ph.D., Associate Professor of Christian Ethics, Pacific School of Religion; David W. Louisell, J.D., Professor of Law, University of California at Berkeley; Donald W. Seldin, M.D., Professor and Chairman, Department of Internal Medicine, University of Texas at Dallas; Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania; and Robert H. Turtle, L.L.B., Attorney, VomBaur, Coburn, Simmons and Turtle, Washington, DC. In an oral history interview, National Commission staff member Barbara Mishkin suggested that pro-life movement concerns in the wake of the 1973 *Roe v. Wade* Supreme Court decision legalizing abortion had influenced the choice of Commissioners. Mishkin noted that Dr. Ryan, selected to Chair the Commission, was Catholic and an obstetrician and so people assumed "that he would put a certain amount of weight, at least, in the balance of things, toward the fetus." Barbara F. Mishkin, interview by Patricia C. El-Hinnawy, 17 June 2004, Belmont Oral History Project, available at <http://www.hhs.gov/ohrp/belmontArchive.html#histArchive2> (accessed 9 March 2010). Interestingly, the *New York Times* obituary for Ryan noted his life-long "firm if soft-spoken" support for women's right to abortion. Eric Nagourney, "Kenneth Ryan, 75, Obstetricians and Leader in Medical Ethics," *New York Times*, 28 January 2002, available at <http://www.nytimes.com/2002/01/28/us/kenneth-ryan-75-obstetrician-and-leader-in-medical-ethics.html> (accessed 9 March 2010). Similarly, in the same interview, Mishkin noted that Albert Jonsen was selected in part because he was a Catholic priest; however, unbeknownst to the staff and his fellow Commissioners, Jonsen had resigned from the priesthood and later married. Jonsen went on to become of the most influential bioethicists in the world. He concurs with Mishkin's assessment that his role as a Catholic priest was influential in his appointment to the Commission. Albert R. Jonsen, *The Birth of Bioethics* (New York: Oxford University Press, 1998). The staff of the National Commission was also influential in shaping the *Reports and Recommendations*. They included: Staff Director, Michael S. Yesley, J.D., Assistant Staff Director, Barbara Mishkin, M.A., pediatric doctor Duane Alexander, philosopher Tom Beauchamp, political scientist Lee Calhoun, sociologist Bradford Gray, and psychologist Miriam Keltz.

proper dosing of drugs in children of various ages, e.g., research on children themselves was a necessity. Furthermore, the Commissioners argued, it was society's moral duty to ameliorate childhood illnesses, as well as to study the roots of adult-onset diseases, and this required conducting more research on children, *even* research that was not directly beneficial to the child subjects of medical experiments. In addition to their internal deliberations, which took place over a series of monthly meetings, the Commissioners reviewed expert reports on the state of research involving children and current laws and ethical regulations governing such research, as well as essays from philosophers of medical ethics offering positions on whether children could legitimately be used as research subjects. In addition, the Commission reviewed the copious correspondence it received from both experts and members of the public, and held an open meeting to gather feedback.¹⁴

The National Commission's Public Hearing on Research on Children, held on 9 and 10 April 1976, in Bethesda, Maryland, provided additional expert and lay testimony in support for research on children. Despite reports of the misuse of institutionalized children, in particular for medical research, most of the researchers and the representatives of parent groups who testified, like the Commissioners themselves, believed that children's participation in research ultimately held greater promise than risk of harm. Sheriden Neimark testified on behalf of the National Society for Autistic Children, emphasizing that over-regulation would be far more harmful than under-regulation of research with children. He stated:

Until recently our children have been all but ignored by the researcher upon whom we now depend totally to find the means for preventing, alleviating or curing their catastrophic disability. Multitudes are suffering daily from the dearth of research, whereas few if any suffer the effects of faulty research, marred by carelessness or heartlessness.¹⁵

The expert testimony agreed with Neimark on the overwhelming value of scientific research for improving the conditions of childhood.

14. Transcript of 11th Meeting, 11 October 1975, Bethesda, Maryland, 33, NCPHSBB.

15. *Ibid.*, 51.

Yale psychologist Edward Zigler went so far as to argue that Head Start and other government-funded programs should be forced to accept research conducted on enrolled children, even over the objections of parents or community groups.¹⁶ As historian Sarah Igo has shown, with the publication of large-scale surveys such as the Gallup polls, Middletown studies, and Kinsey reports, social science research increasingly permeated popular culture in twentieth-century America, leading to a greater acceptance of participation in research as well as a tendency to measure oneself in comparison to the norms produced by such research.¹⁷

Both a general acceptance of children's participation in research and of parents' desire to map their children against research-produced norms were in evidence at the hearings. Several experts cited parents' increasing psychological and monetary investment in their children's averageness in the post-World War II period as a reason alone to permit research on children. William Charlesworth of the Institute of Child Development at the University of Minnesota suggested that the benefits of such research should include "the assurances given anxious parents that their child falls within the range of normality." Presumably for those parents whose children did *not* fall within the normal range, Charlesworth suggested that research was also beneficial because it would transmit "the air of concern to society that there are responsible professional people working . . . [and taking] great pains to study and understand their children."¹⁸

In written testimony, the Black Child Development Institute also expressed concern about black children being stigmatized as abnormal. More skeptical of the mandate of scientific progress, however, the Institute proposed that the black community be involved in all stages of research involving children, from design to implementation, and that only research on children that the black community perceived to be in its own interest be permitted. One of very few dissenting voices, Attorney Annina Mitchell of Michigan Legal Services, recommended that the Commission halt

16. Ibid., 24.

17. Sarah E. Igo, *The Averaged American: Surveys, Citizens and the Making of a Mass Public* (Cambridge, Massachusetts: Harvard University Press, 2007).

18. Transcript of 17th Meeting, 9–11 April 1976, Bethesda, Maryland, 13, NCPHSBB.

all research on children until it could satisfactorily address the abuses of institutionalized children subject to high-risk research that was *not* designed to benefit them. Mitchell discussed the use for drug and vaccine testing of institutionalized children in Michigan-run facilities, which she argued was unethical and done without parental consent or child assent. She cited the example of a state institution for the mentally retarded in Coldwater, Michigan, at which children were involved in a dozen major research projects from 1971 to 1973, including trials of new vaccines for rubella, influenza, para-influenza, meningitis, and mumps. "These financially strapped state facilities," Mitchell charged, "have repeatedly used their control over desirable subject populations to attract research personnel and money, most notably from private drug companies, into state institutions." The results, Mitchell argued, included parents bullied by the institutions in control of their children and children bearing "the burdens of inconvenience and risk." "The reasons for this," she concluded, "are not very difficult to discern—they are cheap, they are accessible, and they are out of the public's sight."¹⁹

The 1956–71 Willowbrook hepatitis studies provided another cautionary example of ethically questionable research on institutionalized children. Located on Staten Island, Willowbrook was a New York State-run facility for children and adults with mental retardation. Severe overcrowding and unhygienic conditions led to the rapid spread of endemic hepatitis among the institutionalized population. Researchers led by Dr. Saul Krugman exposed uninfected children of ages three to eleven to potentially deadly live hepatitis virus in order to study the course of the disease and to develop an effective vaccine. The director of Willowbrook encouraged wait-listed parents, many of whom were desperate to place their severely retarded children in an institution, to sign an ambiguous consent form authorizing their child's participation in the study. Although the studies provided important information on the different strains of hepatitis and did advance research for a vaccine, Krugman and his team were accused of violating the human rights of their severely retarded wards and contributing to the deplorable

19. Ibid., 182–83. See also Annina Mitchell, "Experimentation on Minors: Whatever Happened to Prince V. M?," *Duquesne Law Rev.*, 1975, 4, 919–36.

conditions in which they were maintained.²⁰ After television journalist Geraldo Rivera in his 1972 ABC news exposé *Willowbrook, the Last Great Disgrace* aired footage of disabled children suffering from physical abuse and atrocious living conditions in their wards, Willowbrook became a national symbol for the abuse of institutionalized children, and contributed to public skepticism about the benevolence of scientific experimentation on children. In 1975, the New York Civil Liberties Union won its suit against the State of New York, forcing authorities to enforce decent living conditions for the residents of Willowbrook, and explicitly prohibiting medical experimentation on them.²¹

In order to avoid another scandal and to maintain the public's faith in the beneficence of scientific researchers, the National Commission had to establish standards disallowing investigators from abusing such disadvantaged groups of children. However, the Commissioners, like the majority of the experts who testified before them, believed both that children's participation in research was necessary to advance scientific progress and that it was moral and good—and well within their rightful scope of authority—for parents to volunteer their children as research subjects. How would the Commission draft recommendations which would allow research on children to proceed, while also protecting those most vulnerable from unscrupulous investigators?

INTERNAL DELIBERATIONS

Following the hearing, the Commission's internal debates focused on the areas of autonomy and consent and the limits of acceptable risk. Ramsey's contention that parents' proxy consent for nonbeneficial research was absolutely unethical posed a challenge to the

20. Krugman acknowledged the reality of the unhealthy living conditions, but responded that "We were not qualified to deal with the societal problems, but we believed that we could help control the existing medical problem of hepatitis." He also argued that most residents would become infected with hepatitis within one year of entering Willowbrook, and that he designed his study to minimize risk, although Beecher and other critics were not satisfied with his justification. Quoted in Ross, *Children in Medical Research*, 13–14.

21. David J. Rothman and Sheila M. Rothman, *The Willowbrook Wars* (New York: Harper and Row, 1984), 260–67; Geraldo Rivera, *Willowbrook: A Report on How It Is and Why It Doesn't Have to Be That Way* (New York: Vintage Books, 1972). "NYCLU Ends Willowbrook Disgrace: Better Care Ordered," *Civil Liberties*, September 1975, Box 3, Folder "Meeting #11, 11 October 1975, Tabs 8–11," Tab 10, NCPHSBB.

Commission. In order to permit nonbeneficial research on children, the Commission would have had to retreat from the Nuremberg Code's emphasis on individuals' autonomy as sacrosanct. Instead, the Commissioners turned toward Catholic theology which prioritized individuals' duty to society. During their deliberations, Jonsen posited that "it may well be that departures from autonomy are the only ways in which implementations of a just situation can take place." He cited desegregation of public schools as an example, stating that:

We have imposed risks upon children for reasons of justice. . . . The school integration question . . . is a dramatic instance in which children, both black and white, have been put in situations which are highly risky to their own well-being, fear, threats to their physical life, and so forth, and it is believed by many people that this is justifiable because there is a principle of justice at stake.²²

In making this link between children's participation in school integration—which he deemed a social experiment—and children's obligation to contribute to the greater good of society, Jonsen drew upon the thinking of Catholic theologian Richard McCormick. In his writings, McCormick stressed children's place as members of the human community and parents' roles in educating their children "as to their moral duties," including the undertaking of unselfish service. Thus, parents volunteering their children for participation in research experiments—particularly those that would not directly benefit their subjects but did not entail significant risk to the children—allowed parents to fulfill their obligation to raise their children to contribute to the general welfare. For McCormick, unlike Ramsey, parents' primary duty was not solely to protect children until they reached the age of consent and could make their own decisions, but rather to raise them to be moral beings. McCormick thus concluded that proxy consent for children's participation in research was ethical and just.²³

22. Quoted in the transcript of the 22nd Meeting, 10–12 September 1976, Bethesda, Maryland, 217, NCPHSBB.

23. Richard McCormick, "Proxy Consent in the Experimentation Situation," *Persp. Biol. Med.*, 1974, 18, 2–23. In an interview, Charles R. McCarthy noted that the Commission largely adopted McCormick's framework. Charles R. McCarthy, interviewed by Patricia C. El-Hinnawy, 22 July 2005, Bethesda, Maryland, Belmont Oral History Project, available at <http://www.hhs.gov/ohrp/belmontArchive.html#histArchive2> (accessed 9 March 2010).

In drafts of the Commission's *Report on Research Involving Children*, the Commission staff laid out a framework for conducting research on children that drew heavily on McCormick's reasoning and incorporated both proxy consent and children's assent to participation. The staff paper noted that except in case of national emergency, adults' freedom of choice took precedence over their obligation to aid the common good by participating in research. It would be "untenable," then, to require children and not adults to sacrifice their liberty and to compel their participation as subjects. However, adopting McCormick's thinking, the Commission staff wrote, "to teach [children] regarding their moral duties, to instruct them that they should want to give of themselves, is a different matter entirely from requiring them to do so." Moreover, the authors cautioned, it is a "common error on the part of adults to underestimate a child's capacity for rational thought and intuitive sense of justice." Children should be given "an opportunity to choose, to the extent they are able, whether or not to participate in research, and whether or not to continue participation." Therefore, the Commission concluded, both parental or guardian proxy consent *and* a child's assent should be required conditions for children's participation in research.²⁴ Not all of the Commissioners were satisfied with this approach, however, because while it succeeded in encouraging research on children, it seemed to some to promote the autonomy of young children at the expense of their protection. While the Commissioners had prided themselves on issuing unanimous recommendations in the past, they would find themselves unable to reconcile their views on this issue.

THE NATIONAL CONTEXT: CIVIC AND PROTECTED CHILDHOODS

The Commissioners' divisions over the protection of children and the promotion of their autonomy resonated with important changes in understandings of childhood in American culture in the post-World War II period. Both the scope of parental authority and the appropriate role of children within the family and the

24. "Children and the Mentally Disabled as Research Subjects," pp. 21–24, 3 October 1975, Box 7, Mtg. 17, Tab 9, NCPHSBB.

nation were major sources of national concern during the post-World War II period.²⁵ Despite—or perhaps, because of—post-war abundance, many Americans felt that it was essential to ensure a well-adjusted future for the nation's youth.²⁶ Millions of nervous Americans turned to Dr. Spock's bestselling *Baby and Child Care* for advice on how to exercise parental authority and discipline while at the same time encouraging their children's development into independent, mature adults. Children of the post-World War II baby boom enjoyed not only great material wealth and more time in school, but also a high level of parental nurturing.

Dr. Spock urged mothers in particular to express their love for their children and to devote their time and thought to child-rearing. Based on his team's study of Boston-area mothers in 1951–52, sociologist Robert Sears reported that the majority of mothers had absorbed Dr. Spock's recommendations; they remained focused “rather continuously” upon their children. The prominence of Dr. Spock and of debates over children's participation in consumer culture, among other issues, reflected an increasingly child-centered American culture. In the late nineteenth and early twentieth centuries, progressive reformers aimed to make childhood a protected time isolated from the ills of participation in an industrial capitalist workforce as well as from exposure to sexuality and vice. It was not until the prosperous post-World War II period, however, that the Progressive vision of childhood devoted solely to schooling and play became achievable for most American families. During the

25. Of many important works on Cold War culture, consumerism, the family, and gender, see in particular James Gilbert, *A Cycle of Outrage: America's Reaction to the Juvenile Delinquent in the 1950s* (New York: Oxford University Press, 1986); Elaine Tyler May, *Homeward Bound: American Families in the Cold War Era* (New York City: Basic Books, 1988); Susan Douglas, *Where the Girls Are: Growing up Female with the Mass Media* (New York: Times Books, 1994); Tom Engelhardt, *The End of Victory Culture: Cold War America and the Disillusioning of a Generation* (New York: Basic Books, 1995); Lynn Spigel, *Make Room for TV: Television and the Family Ideal in Postwar America* (Chicago: University of Chicago, 1992); and K. A. Cuordileone, *Manhood and American Political Culture in the Cold War* (New York: Routledge, 2005). Influential sociological works on American masculinity during the early Cold War include David Riesman, *The Lonely Crowd: A Study of the Changing American Character* (New Haven: Yale University Press, 1950) and William Hollingsworth Whyte, *The Organization Man* (New York: Simon and Schuster, 1956).

26. Michael Zuckerman, “Dr. Spock: The Confidence Man,” in *The Family in History*, ed. Charles E. Rosenberg (Philadelphia: University of Pennsylvania, 1975), 179–207.

1950s and 1960s, in short, American parents “placed the welfare of the children at the center of family life.”²⁷

While elevating children’s welfare as the goal of family life, American parents also put their children forward as risk-taking agents of change during the post-World War II decades. In doing so, Americans embraced a new understanding of childhood, which we call “civic childhood,” to denote both parents’ commitment to improving their children’s welfare and their expectations that their children would be expected to make sacrifices to benefit the greater good.²⁸ In 1954, the parents of 1.8 million American school children answered March of Dimes head Basil O’Connor’s call to act morally and enable their children to benefit “generations to come” by participating in polio vaccine tests.²⁹ The polio vaccine test, the largest medical experiment in American history, proved successful and, according to historian Steven Mintz, ultimately “instilled a lasting faith in the power of medical research to eradicate children’s diseases.” Other medical advances of the mid-twentieth century, including “sulfa drugs, penicillin, insulin, immunization against whooping cough and diphtheria, new treatments against tetanus and fluoride” dramatically improved the health of American children and, like the polio vaccine, reinforced a positive view of medical research on children.³⁰ The publicity surrounding the triumph of the polio vaccine reaffirmed the American public’s

27. Charles E. Strickland and Andrew M. Ambrose, “The Baby Boom, Prosperity, and the Changing Worlds of Children, 1945–1963,” in *American Childhood: A Research Guide and Historical Handbook*, ed. Joseph M. Hawes and N. Ray Hiner (Westport, Connecticut: Greenwood Press, 1985), 533–86, 538.

28. The authors are grateful to the anonymous reviewer for suggesting this term, civic childhood. Sociological theorist John O’Neill uses the term civic childhood to refer to a secure childhood enabled by public support for families, education, health care, and social services that would enable a child to thrive and achieve full citizenship, in accordance with T. H. Marshall’s understanding of social citizenship. See John O’Neill, *Civic Capitalism: The State of Childhood* (Toronto: University of Toronto Press, 2004), and T. H. Marshall, *Citizenship and Social Class and Other Essays* (Cambridge: Cambridge University Press, 1950). William Strauss and Neil Howe also use the term civic to describe one of four age peer groups, or generations, that they argue cyclically repeat throughout U.S. history. William Strauss and Neil Howe, *Generations: The History of America’s Future, 1584 to 2069* (New York: William Morrow and Company, 1991). We are using the term in a different way, to refer to the sense of public obligations and well as rights conferred on children as citizens in the post-World War II United States.

29. David Oshinsky, *Polio: An American Story* (New York: Oxford University Press, 2005), 6, 190.

30. Steven Mintz, *Huck’s Raft: A History of American Childhood* (Cambridge, Massachusetts: Harvard University Press, 2004), 279.

belief in scientific progress, and also highlighted the crucial role of the nation's children, as potential and actual victims of the disease as well as voluntary protagonists in the fight to conquer the illness.

A decade later, the civil rights movement provided another dramatic illustration of children's role as heroic protagonists in achieving national progress. In what historians now identify as a climactic turning point in the civil rights movement, in the spring of 1963, the schoolchildren of Birmingham, Alabama, confronted violent repression by the police force of Public Safety Commissioner Bull Connor. In demonstrations "organized, designed, and controlled . . . for optimum media coverage" more than two thousand school children, mostly between the ages of thirteen and sixteen but including some as young as six, marched, picketed, and prayed even as Connor brought out police dogs and ordered his firemen to direct high pressure water hoses at them. Televised nationally, the children's bravery and Connor's barbarism won supporters from around the world for the civil rights movement. The signal role of children in the Birmingham protests was made tragically poignant the following September when white supremacists bombed the Sixteenth Street Baptist Church in Birmingham, killing four girls, ages eleven and fourteen, who had been attending Sunday school classes at the church.³¹

Despite the demonstrated risk to children from white supremacist violence, African American parents allowed their youth to fight for racial equality and social justice. As Jonsen noted in the National Commission's deliberation of children's rights and children's duty, children, especially African American youth, bore much of the brunt of highly contested school desegregation efforts. Ranging from the Little Rock Nine, the group of African American high schools students who withstood intense harassment and integrated Little Rock Central High School in 1957, to courageous African American youths who faced vigorous resistance to their attendance of previously all-white schools in several neighborhoods in Boston in 1974, schoolchildren again and again took center stage as highly

31. Glenn Eskew, *But for Birmingham: The Local and National Movements in the Civil Rights Struggle* (Chapel Hill: University of North Carolina Press, 1997), 272; Henry Hampton, "Episode 4: No Easy Walk (1962–1966)," of the documentary series *Eyes on the Prize: America's Civil Rights Years* (1986).

visible protagonists in the nation's ongoing battle over desegregation. In the 1950s and 1960s in cities including Boston, New York, and Los Angeles, African American, Mexican American, and Puerto Rican parents and their children enacted civic childhood by staging massive school boycotts to protest racial segregation and to claim the right to high-quality public education.³²

Students' civil rights and anti-war activism in schools played an important role in the emergence of the children's rights movement in the 1960s and 1970s. In 1969, in considering a case in which children wore armbands to school to protest the Vietnam War, the Supreme Court ruled in *Tinker v. Des Moines* that First Amendment rights applied to students. In addition to desegregation and the right to free speech, students and children's rights advocates claimed a more inclusive right to education. Latino student demonstrators demanded, and won, bilingual education, funded initially by Great Society programs and reinforced by the Supreme Court's 1974 *Lau v. Nichols* decision requiring San Francisco to provide English instruction to Chinese speaking students. In 1975 Congress passed the Education for All Handicapped Children Act, mandating that public schools provide all students with disabilities with a free education suited to their needs. These reforms, along with Section 504 of the 1973 Rehabilitation Act prohibiting discrimination against the disabled, expanded the right to a protected childhood supported by state funding to new groups of children.³³

While extending protection to new groups, children's rights advocates in the 1960s and 1970s, as Mintz suggests, broke new

32. Adina Back, "Exposing the 'Whole Segregation Myth': The Harlem Nine and New York City's School Desegregation Battles," in *Freedom North: Black Freedom Struggles outside the South, 1940-1980*, ed. Jeanne F. Theoharis and Komozi Woodard (New York: Palgrave Macmillan, 2003), 65-92; Jeanne F. Theoharis, "'I'd Rather Go to School in the South': How Boston's School Desegregation Complicates the Civil Rights Paradigm," in *Freedom North*, ed. Theoharis and Woodard, 125-52; Jeanne F. Theoharis, "'They Told Us Our Kids Were Stupid': Ruth Batson and the Educational Movement in Boston," in *Groundwork: Local Black Freedom Movements in America*, ed. Jeanne F. Theoharis and Komozi Woodard (New York: New York University Press, 2005), 17-44; Jeanne F. Theoharis, "W-A-L-K-O-U-T: High School Students and the Development of Black and Brown Power in Los Angeles," in *Neighborhood Rebels: Black Power at the Local Level*, ed. Peniel Joseph (New York: Palgrave Macmillan, 2009), 107-30. For additional information on children and youth in the civil rights movement, see David Halberstam, *The Children* (New York: Random House, 1998), and Diane McWhorter, *Carry Me Home* (New York: Simon and Schuster, 2001).

33. Mintz, *Huck's Raft*, 323-28.

ground in insisting that children be presumed competent before the law. The “children’s rights revolution” led to reforms including the right for children accused in juvenile courts to have legal counsel, to cross-examine witnesses, and to remain silent; rights for minors to make certain medical or educational decisions on their own; and a right for children to have their own preference taken into consideration in decisions over adoption, custody, divorce, termination of parental rights, or child abuse. Reversing the tradition of presuming children’s incompetence before the law, children’s rights advocates argued in favor of children’s self-determination in “decisions about motherhood, abortion, schooling, cosmetic surgery, venereal disease treatment, sexuality, or any decision that would significantly affect the child’s future.” Although courts upheld the rights of children and adolescents to birth control, abortion, and treatment for sexually transmitted diseases, questions of sexual freedom remained the most controversial aspect of the children’s rights revolution. Nonetheless, the changes in custom and law granting adolescents and young adults greater autonomy would prove lasting: the twenty-sixth amendment to the U.S. Constitution, ratified on 1 July 1971, lowered the voting age from twenty-one to eighteen, where it has since remained.³⁴

As the children’s rights movement enhanced the right of self-determination for children generally, another social movement, led by parents of mentally retarded children, emphasized the need to protect children from harm. Improvements in medical treatment during and after World War II resulted in mentally retarded children’s survival into adulthood becoming commonplace, but parents of mentally retarded children had few options for quality care in the 1950s and 1960s. Many of these parents formed interest groups aimed at deinstitutionalization and federal funding for research and care of disabled children.³⁵ Parent groups found an ally in the

34. Michael Foley, ed., *Dear Dr. Spock: Letters about the Vietnam War to America’s Favorite Baby Doctor* (New York: New York University Press, 2005), and Thomas Maier, *Dr. Spock: An American Life* (New York: Harcourt Brace & Co., 1998).

35. Burton Blatt and Fred Kaplan, *Christmas in Purgatory: A Photographic Essay on Mental Retardation* (Boston: Allyn and Bacon, 1966), v; Leslie J. Reagan, “Rashes, Rights, and Wrongs in the Hospital and in the Courtroom: German Measles, Abortion, and Malpractice before *Roe* and *Doe*,” *Law Hist. Rev.*, 2009, 2, 241–80; and Leslie Reagan, *Dangerous Pregnancies: Mothers, Disabilities, and Abortion in Modern America* (Berkeley: University of California Press, 2010).

Kennedy administration, which advanced attention to and improvements in the treatment of mentally retarded children.³⁶

Polio survivors also took on leadership roles in the emerging disability rights movement in the 1960s and 1970s. In contrast to the concept of civic childhood operating during the polio vaccine trials and the civil rights movement, which had emphasized children's role as volunteers working toward social progress, the disability rights movement stressed society's obligation to protect children from harm—especially from the harms that were documented as routine occurrences in institutions prior to this period of reform, including using institutionalized children as research subjects because of convenience.³⁷

THE REPORT

In the Commission's deliberations and final report, the influence of both the children's rights revolution and the renewed emphasis on child protection generated by the disability rights movement is evident. The Commissioners reviewed an impressive survey of research on related topics, including child development and psychology, pediatric research practices, recent law decisions involving children, the status of institutionalized children, and ethicists' views on research on children. Ultimately, the majority of the Commissioners agreed that "recognition of the capacity and the right of children to make their own determination regarding participation in research" required children aged seven and older to assent to participation in research. The Commissioners noted that "this conclusion is consistent with a recent trend in both law and philosophy to respect the rights of children and to encourage their development toward assuming responsibility for their decisions." Taking children's wishes into consideration, while requiring parental permission, they reasoned, was the best way to resolve the

36. Eunice Shriver remained committed to the cause of improving the lives of people with mental retardation and in 1968, founded the Special Olympics. Edward Shorter, *The Kennedy Family and the Story of Mental Retardation* (Philadelphia: Temple University Press, 2000), 78–87; Fred J. Krause et al., *President's Committee on Mental Retardation: A Historical Review, 1966–1985* (Washington, DC: Presidents Committee on Mental Retardation, 1986); Martin Weil, "Rosemary Kennedy, 86; President's Disabled Sister," *The Washington Post*, 8 January 2005, B06.

37. Julie Silver and Daniel Wilson, *Polio Voices: An Oral History from the American Polio Epidemics and Worldwide Eradication Efforts* (Westport, Connecticut: Praeger, 2007), 98.

“important ethical problems about third party consent” raised by Ramsey and others. Doing so encouraged the developing “moral responsibility of children” while involving adults, who did have capacity for informed consent, in the final decision.³⁸ As we will see below, however, two members of the Commission, influenced by the child protection movement, felt that parental permission alone did not provide enough protection to children involved as research subjects. We will first summarize the Report’s recommendations, adopted by the nine Commissioners in the majority, and then discuss the two dissenting opinions.

In his letter to President Jimmy Carter accompanying the Commission’s report, *Research Involving Children*, Chairman Kenneth Ryan stated that “the involvement of children in research raises particular ethical concerns because of their reduced autonomy and their incompetency to give informed consent.” Despite these concerns, he noted, research on children must proceed in order to “develop new treatment or preventive methods for conditions that jeopardize the health of children” and to protect them from “accepted though unvalidated practices that may be harmful to them.”³⁹ The Commission defined children as “persons who have not attained the legal age of consent to general medical care [as opposed to reproductive health care or drug abuse treatment] as determined under the applicable law of the jurisdiction in which the research will be conducted.”⁴⁰ The Report then laid out ten recommendations, beginning with its endorsement of research on children, in order to advance “the health and well-being of all children,” provided the research met with the following conditions. [See Table 1 for a summary of the recommendations.]

In order to be ethically acceptable, Recommendation 2 mandated that all research on children be reviewed by an IRB and found to be “scientifically sound and significant;” to minimize risk by using “the safest procedures” possible; and to protect the privacy of children and their parents and maintain the confidentiality of data. Additionally, when appropriate, scientists were required to conduct

38. U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research Involving Children*, 129.

39. *Ibid.*, i.

40. *Ibid.*, xix.

TABLE I

Summary of NCPHS Recommendations for Research Involving Children

<i>Class of children</i>	<i>Type of research</i>	<i>Conditions on research</i>
All normal children*; Recommendations 1, 2, 3, and 7	Does not involve greater than minimal risk to children	IRB has determined that research is scientifically sound and significant; where appropriate, studies conducted first on animals and adult humans, then on older children, prior to involving infants; risks are minimized by using safest procedures consistent with sound research design and by using procedures performed for diagnostic or treatment purposes whenever feasible; adequate provisions are made to protect the privacy of children and their parents, and to maintain confidentiality of data; and subjects will be selected in an equitable manner. Children over age seven must assent and parent or guardian must give permission. The objection of a child of any age to participation in research is binding unless the intervention holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of research. Parents or guardians should be sufficiently involved in research to understand its effects on their children and be able to intervene, if necessary

continued

TABLE I *Continued*

<i>Class of children</i>	<i>Type of research</i>	<i>Conditions on research</i>
All normal children; Recommendation 4	More than minimal risk that holds prospect of direct benefit for individual subject or monitoring procedure required for the well-being of the subject	In addition to above conditions, risk must be justified by anticipated benefit to subjects and the relation of anticipated benefit to such risk must be at least as favorable to the subjects as that presented by available alternative approaches
All normal children; Recommendation 5	More than minimal risk but with no prospect of direct benefit for individual subjects, or a monitoring procedure not required for the well-being of the subjects	In addition to first set of conditions, IRB must determine that risk represents a minor increase over minimal risk; such intervention or procedure represents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, psychological, or social situations, and is likely to yield generalizable knowledge about the subjects' disorder or condition
All normal children; Recommendation 6	More than a minor increase over minimal risk without direct benefit to subjects	In addition to first set of conditions, research must present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children; and the conduct of the research must not violate the principles of respect for persons, beneficence, and justice. Research must be approved by a national ethical advisory board and, following opportunity for public review and comment, by the Secretary of the responsible federal department

Children who are wards
of the state;
Recommendation 9

Research must be related to
their status as orphans,
abandoned children, and the
like or conducted in a
school or similar group
setting in which the
majority of children
involved as subjects are not
wards of the state
All research

In addition to the first set of requirements, an advocate
for each child must be appointed and given the
opportunity to intercede that would normally be
provided by parents

Children who reside in
institutions for the
mentally infirm or who
are confined in
correctional facilities;
Recommendation 10

In addition to the first set of requirements, the
research conditions must conform to the conditions
regarding research on the institutionalized mentally
infirm or on prisoners

*The Commission used the term “normal” in this context to indicate children who lived with a parent or guardian, and had a good
relationship with that parent or guardian.

studies “first on animals and adult humans, then on older children, prior to involving infants.” Unlike adults, research on children required satisfying “a standard of scientific significance,” because “these subjects are less capable than adults of determining for themselves whether to participate.” Older children are preferable to younger children, the Commission determined, because they are “less vulnerable” and “better able to understand and consent to participation,” as well as “more able to communicate about any physical or psychological effects of such participation.” The Commission also recommended that subjects “be selected in an equitable manner, avoiding over-utilization of any one group of children based solely upon administrative convenience or availability of a population living in conditions of social or economic deprivation.”⁴¹

Recommendations 3 through 6 detailed the extent of risk permissible in research on children, assigning additional conditions to children’s participation in research as the risk level increased and direct benefit to children declined. For example, research involving more than minimal risk and without direct benefit to the participant, but with the potential to “understand, prevent, or alleviate a serious problem affecting the health or welfare of children” could be permitted only if it was approved by a national ethical advisory board and the secretary of the responsible federal department, and if Congress was notified and had “reasonable opportunity” to take action on the proposed research. In this case, the Commission determined, “only research of major significance, in the presence of a serious health problem, would justify the approval of the research.” In contrast, research involving minimal risk could be conducted with local IRB approval and provisions for the assent of the children involved and the permission of their parents; and research involving more than minimal risk but with the prospect of direct benefit for the subject could be approved by a local IRB provided that in addition to meeting the preceding conditions, “the relation of anticipated benefit to such risk is at least as favorable to the subjects as that presented by available alternative approaches.”⁴²

41. Ibid., 2–4.

42. Ibid., 4–12.

Recommendations 7 and 8 detail parental and guardian permission requirements, as well the need to secure—when “capable”—the assent of child participants in research. Choosing its language carefully, the Commission favored parental or guardian permission rather than consent, “in order to distinguish what a person may do autonomously (consent) from what one may do on behalf of another (grant permission).” Parental permission was “normally” required for the participation of children in research projects, in addition to the assent of children aged seven years or older (here, “assent” distinguishes “a child’s agreement from a legally valid consent”). The Commission noted that “a child’s objection to participation in research should be binding unless the intervention holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.” The Commission defined guardians as those legally appointed as well as “others who care for a child in a reasonably normal family setting.”⁴³

Infants and small children—because of their “dependent” status, “the traditional role of parents as protectors, and the general authority of parents to determine the care and upbringing of their children”—could require additional safeguards to be determined by IRBs, such as requiring parents or guardians to be present during the research. Generally, the Commission observed, “parents or guardians should be sufficiently involved in the research to understand its effects on their children and be able to intervene, if necessary.” Side-stepping the debates over the rising incidences of single motherhood and single mother’s rights, the Commission recommended that “Parental or guardian permission should reflect the collective judgment of the family that an infant or child may participate in research.” The riskier the research, the Commission stated, the greater the need to involve both parents in giving permission, unless one parent is “deceased, unknown, incompetent or not reasonably available, or the child... belongs to a single-parent family.”⁴⁴

Children seven years of age or older “are generally capable of understanding the procedures and general purpose of research and

43. *Ibid.*, 12–14, 16.

44. *Ibid.*, 14–17.

of indicating their wishes regarding participation,” the Commission determined. Furthermore, “as children mature, their ability to perceive and act in their own best interest increases; thus, their wishes with respect to such research should carry more weight.” Historically, the Commission noted in defense of Recommendation 6, “age seven has significance in both canon and common law; it is a traditional age of demarcation between very restrictive and more liberal distributions of rights and responsibilities to children.”⁴⁵ If a school-age child disagreed with his or her parents over participation in research that held promise of direct benefit to the child, the Commission recommended asking a “third party” to “discuss the matter with all concerned”—although parents in the end retained the legal ability to override their children’s decisions.⁴⁶

Parental permission could be waived, the Commission recommended, in cases of “mature minors” who might “reasonably assume” similar risk-levels on their own (i.e., confidential reproductive health care or addiction treatment) or in the case of “neglected or abused children” or “children designated by their parents as ‘in need of supervision’”; or children whose parents “are legally or functionally incompetent.” The Report noted that recent Supreme Court decisions regarding the constitutional right of minors to obtain abortion and contraception without the consent of their parents or guardians left the issue of “the unit of autonomy at stake” and that these issues remain “to be decisively studied.” The Commission did not attempt to settle these controversial issues itself, but rather recommended that researchers follow applicable state laws governing the age at which mature minors could receive reproductive or mental health care without their parents’ involvement.

45. Kenneth Ryan to Joseph Califano, 20 October 1978, Record Group 443 05 006, Box 81, Folder Res 3-4-D Report on Research Involving Children (1977), National Archives and Records Administration, College Park, Maryland.

46. Contemporary—as well as subsequent—empirical research from developmental psychology also supported the National Commission’s recommendation, finding that children age seven and up are generally able to participate in making important life decisions, including participating in research. Lois A. Weithorn and David G. Scherer, “Children’s Involvement in Research Participation Decisions: Psychological Considerations,” in *Children as Research Subjects: Science, Ethics and Law*, ed. Michael A. Grodin and Leonard H. Glantz (New York: Oxford, 1994), 133–79.

Declaring that “no single mechanism” can be “substituted” for parental permission, the Commission suggested that at times the consent of a mature minor is sufficient, while at other times a court’s intervention or the appointment of a surrogate guardian in the form of a social worker might be necessary. Recommendation 9 stipulated that children who are wards of the state should not participate in research involving more than minimal risk unless it was “related to their status as orphans, abandoned children, and the like,” or “conducted in a school or similar group setting in which the majority of children involved as subjects are not wards of the state.” Recommendation 10 required that “children who reside in institutions for the mentally infirm or who are confined in correction facilities should participate in research only if the research met the Commission’s additional requirements for research with the mentally infirm and with prisoners.”⁴⁷

INTERNAL DISSENT AND PUBLIC REACTIONS

Commissioners Robert Turtle and Robert Cooke authored dissenting opinions to *The Report on Children*. Both departed from the majority decision in Recommendation 5, which allows for research involving a “minor increase” over “minimum risk” which poses no immediate benefit for the child subject, but which holds out the prospect of future advancements for children suffering from the same disorder or condition. Because sick children “are subjected to greater risks incident to their condition or necessary treatment,” Turtle feared that the “minor increase” over “minimum risk” provision of Recommendation 5 would pave the way for increasing amounts of research done on sick children to their detriment. He proposed that sick children, like institutionalized children, should receive additional special protections. Turtle noted that sick children’s own cognitive and physical functions may be impaired due to their illness, and thus they may not have the ability to offer meaningful assent to participation in research. Moreover, children who experience prolonged treatment for their illness “develop a special

47. U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research Involving Children*, 12–20, 77–78. The Supreme Court decisions were *Planned Parenthood of Central Missouri v. Danforth* (1976) and *Carey v. Population Services International* (1977).

relationship with their therapist and the medical staff” and this relationship might sway children to assent to participation in research. Finally, Turtle noted, “the emotional impact of a serious illness in the family may lead to a breakdown of the judgmental and perceptive relationships within the normal family unit,” resulting in “diminishing of normal parental judgment and discretion” and an inability to offer informed consent in the form of parental permission for their child’s participation in research.⁴⁸

Cooke also questioned the ability of parents to offer reasoned permission for their children to participate in research, but he suggested that the Recommendation would be acceptable if parents who volunteered their children participated in all steps of the research programs alongside their children, and could withdraw them at any time. Additionally, Cooke objected to Recommendation 5 because the Commission had left the decision of what constitutes a “minor increase” over minimum risk to be determined by IRBs, which, he argued, could lead to “considerable disparity” in interpretation, and significant risk to the child subject. In leaving the judgment of acceptable risk this open, Cooke would later charge, the Commission was “cavalier” in response to its mandate to protect children and the mentally ill. He explained, “Children don’t have autonomy, and the retarded don’t have autonomy. And so—they don’t vote and all of the rest of the things in our society. So they, I think, have been abused over the years, totally inappropriately.”⁴⁹

In contrast, in supporting Recommendation 5, the majority of the Commissioners wrote that such research was permissible in part because it could provide “substantial future benefits” to children and in part because “permission to allow such research lies within the scope of parental authority.” This Recommendation, the majority opinion noted, concurred with the “presumption” that “parents are generally the best protectors of their children” and

48. *Ibid.*, 150–51. In his printed dissenting statement, Turtle noted that “throughout the Commission’s deliberations, I have expressed many reservations about the involvement of children as research subjects” (*ibid.*, 146). Turtle died in 1978, shortly before the last meeting of the National Commission, and therefore was not included in the Belmont Oral History Project. We have been unable to determine if personal experience shaped Commissioner Turtle’s concerns over children’s participation in research.

49. *Ibid.*, 138–54. Robert E. Cooke, interviewed by Bernard A. Schwetz, 15 May 2004, Belmont Oral History Project, available at <http://www.hhs.gov/ohrp/belmontArchive.html#histArchive2> (accessed 9 March 2010).

should therefore generally be able to decide whether to volunteer them for research or not.⁵⁰ Part of what was at stake in these debates, then, was the understanding of the child as an individual—with autonomous interests and rights—versus as a member of the family, whose interests would be determined by the parents.

In a 2004 interview, Cooke explained how he had come to his dissenting opinion, linking it to his previous life experiences as a parent and as Chairman of the Department of Pediatrics at Johns Hopkins School of Medicine. Cooke's interest in research ethics stemmed from his life-long commitment to better conditions for his two children who were born "profoundly retarded," as well as from his experiences as a young pediatric researcher conducting a study on orphaned black babies that involved discomfort and risk for the infants, and which he later recognized as unethical. Reflecting on his long career in research pediatrics, Cooke concluded parents do not necessarily have the same interests as their children, and are not necessarily the best protectors:

Over the years I'd seen research done on children where the parents agreed with enthusiasm, that was really terribly hazardous to the children . . . parents frequently can agree to things, either because they don't understand the problem, or because they are so concerned about their children, the problem, that they'd like to do almost anything to correct it. And that's been the history of Downs Syndrome—one intervention after another that may be harmful to the child; very enthusiastically endorsed by the parents.⁵¹

Although Cooke dissented from one of the ten recommendations, he and the rest of the Commissioners agreed that children do indeed have rights. Their recommendation that no research be permitted on a child over the age of seven without the child's assent, unless it was for "essential therapy" necessary for the child's health, was interpreted by the medical community as "cracking down" on the use of

50. U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research Involving Children*, 142.

51. Although Cooke did not discuss his role for more than thirty years as a scientific advisor to the Kennedy Foundation in the area of research on mental retardation or his service on the President's Panel on Mental Retardation during the interview, those experiences also likely contributed to his emphasis on the protection of children who are research subjects. Shorter, *The Kennedy Family and the Story of Mental Retardation*, 73–74, and Robert E. Cooke interview.

children in research.⁵² These tighter standards would impact more than 200 clinical trials involving 158,000 children at the National Institutes of Health alone, and were opposed by leading pediatric researchers, including the Director of the Children's Hospital of the National Medical Center in Washington, DC, who argued that the age of fourteen, not seven, would mark an appropriate stage to seek a child's assent.⁵³ In a letter to Commissioner Seldin, Paul McEnery of the Children's Hospital Research Foundation warned that the National Commission's requirement of children's assent would make research on children so difficult that "in their attempt to protect children the National Commission may be depriving all future children of their right to future medical advances in presently unconquered pediatric disorders."⁵⁴

In correspondence directed to both the Commission and to the NIH, some pediatric researchers opposed the recommendation for children's assent beginning at age seven on the grounds that it would disrupt parent-child relationships and undermine parental authority. The IRB of the Children's Hospital Medical Center in Cincinnati, Ohio, contended not only that children as young as seven lacked the "abstract reasoning" necessary to weigh risks and benefits; but also that "if the wishes of the parents and their children are at odds with respect to participation in a research study, the emotional conflict created may have both short and long-term psychological implications." Parents can require many things of their children, one NIH team pointed out, and it is "unclear, why, with respect to participation in research, the intrusion of a governmental regulation should be allowed to create a new sense of autonomy."⁵⁵ Writing to the National Commission in his multiple roles as a "father of four," "practicing pediatrician," and "an academic pediatrician interested in furthering meaningful research in

52. "U.S. Cracking Down on Using Children in Research," *The Medical Post*, 21 June 1977, Box 17, Mtg. 33, Tab 12, NCPHSBB.

53. "Recommend Guidelines for Research Involving Children," *Pediatric News*, July 1977, Box 17, Mtg. 33, Tab 12, NCPHSBB. Robert H. Parrott, Director, Children's Hospital, to Robert E. Cooke, 3 June 1977, Box 17, Mtg. 33, Tab 13, NCPHSBB. See also "Federal and University Regulations on Research Termed Too Restrictive," *Pediatric News*, April 1978, Box 21, Mtg. 42, Tab 1, NCPHSBB.

54. Paul T. McEnery to Donald Seldin, 9 March 1978, Box 21, Mtg. 42, Tab 11, NCPHSBB.

55. Jennifer Loggie and Edward Pratt to D. T. Chalkley, NIH, 6 March 1978, Box 21, Meeting 42, Tab 11, NCPHSBB.

childhood,” William K. Schubert urged the Commissioners to drop the requirement for children’s assent lest it create “emotional problems in the family which are far more severe than the research problems that the law is intended to control.”⁵⁶ In contrast, Elizabeth Levinson, a therapist who worked with children with mental retardation and their parents, wrote to urge the Commission not to give parents too much authority over their children’s medical treatment, asking, “Can we give to all parents complete control over all decisions to be made for their children and even over all that may be found out concerning the children in relation to their families . . . ? The decision to give all parents complete control and an absolute right to privacy unless law-breaking is involved, seems based on the assumption either that all parents are good and wise, or that children themselves have no rights.”⁵⁷ As these letters reveal, the National Commission had entered into widely contested debates around parental authority and children’s roles in the family, debates which remain lively today.

CONCLUSION

As young Americans claimed more autonomy and less need for protection, the National Commission, too, enhanced the autonomy of children and adolescents, granting them the ability to assent to research from the age of seven up. Treating children as little adults in the context of their participation in research could only seem sensible within a social climate that granted young people increased say in decision-making over their own lives. For the most part, the gains in independence granted to youths in the 1960s and 1970s have remained intact or expanded.

Today, researchers who conduct experiments involving children are governed by the Department of Health and Human Service’s federal regulation 45 CFR 46, Subpart D, “Additional Protections for Children Involved as Subjects in Research,” which codified the

56. William K. Schubert to Donald Seldin, 8 March 1978, Box 21, Meeting 42, Tab 11, NCPHSBB.

57. Elizabeth Levinson to Kenneth Ryan, 15 September 1975, Box 3, Meeting 11, Tab 11, NCPHSBB. Commissioner Robert Cooke discusses the issue of incompetent parents, as well as other conditions that make children particularly vulnerable, in Robert E. Cooke, “Vulnerable Children,” in *Children as Research Subjects: Science, Ethics and Law*, ed. Michael A. Grodin and Leonard H. Glantz (New York: Oxford University Press, 1994), 193–214. See also Shorter, *The Kennedy Family and the Story of Mental Retardation*.

recommendations of the National Commission. The Commission's final recommendations remain intact, with few modifications.⁵⁸ In the aftermath of Tuskegee and numerous other examples of unethical research, Commissioners Turtle and Cooke voiced concerns over the exploitation of children in their dissent from the Commission's report. Following the onset of the AIDS epidemic in the early 1980s and the urgent lack of treatment options, however, public concern shifted from the protection of human subjects of research, to their inclusion in scientific experimentation.⁵⁹ In the late 1990s, amid concerns from pediatricians, researchers, and eventually Congress that children were being excluded from biomedical research to their detriment, the NIH changed its policy to require that children "be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them."⁶⁰ The NIH policy of inclusion does not remove 45 CFR 46's requirements on children's participation in research. Recently, in concluding her survey of pediatric research studies, medical ethicist Lainie Friedman Ross argued that "the ideological shift from a focus on access has exposed children to significant and unnecessary risks."⁶¹ These findings suggest that the

58. One modification to the original recommendations that is perhaps significant is that instead of setting age seven as the age at which assent is required, 45 CFR 46 adopted a more flexible rule that "in determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate." The text of 45 CFR 46 is available at <http://www.nihtraining.com/ohsrsite/guidelines/45cfr46.html#46.408> (accessed 9 March 2010). Additionally, the regulations include an exemption for "normal educational practice," including research on the effectiveness of instructional strategies as well as for educational testing, which exempts a substantial portion of research on children from review. Other federal agencies also use the National Commission's recommendations for research on children. For example, the U.S. Department of Education adopted the National Commission's recommendations for research on children as 34 CFR 97 Subpart D, available at <http://www.ed.gov/policy/fund/reg/humansub/part97.html> (accessed 9 March 2010). Correspondence between the National Commission, the National Institutes of Health, and HHS regarding these changes is located in Record Group 443 05 006, Box 81, Folder Res 3-4-D Report on Research Involving Children (1977), National Archives and Records Administration, College Park, Maryland.

59. Patricia A. King, "Justice Beyond Belmont," in *Belmont Revisited: Ethical Principles for Research with Human Subjects*, ed. James F. Childress, Eric M. Meslin, and Harold T. Shapiro (Washington, DC: Georgetown University Press, 2005), 136-47.

60. NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects, 6 March 1998, <http://grants1.nih.gov/grants/guide/notice-files/not98-024.html> (accessed 9 March 2010).

61. Ross, *Children in Medical Research*, 234.

pendulum may be once again swinging toward a need for greater protection of research subjects, and in particular, those in vulnerable groups, such as children.⁶²

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62. Barry Bozeman and Paul Hirsch, "Science Ethics as a Bureaucratic Problem: IRBs, Rules and Failures of Control," *Policy Sci.*, 2006, 38, 269–91.