Contemporary Directions in Research Ethics in Pediatric Psychology: Introduction to the Special Section

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The importance of research on ethics in the field of pediatric psychology is multifaceted: research on a wide range of pediatric studies raises continuing ethical concerns related to informed consent, including parental permission and assent (Appelbaum, Lidz, & Grisso, 2004; Brody, Scher, Annett, & Pearson-Bish, 2003; Drotar, 2008; Masty & Fisher, 2008; Miller, Drotar, & Kodish, 2004; Miller & Nelson, 2006; Vitiello, 2008). Moreover, genetic and genetic testing research (Patenaude, 2005), prevention and intervention research with high-risk pediatric populations (Bauman, Sclafane, LoIancono, Wilson, & Macklin, 2008), and comparative effectiveness research that compares two active treatments (Stines & Feeney, 2008; Tunis, Benner, & McClellan, 2009) raise challenging new ethical issues.

Research on the ethical conduct of psychological research with children and adolescents is needed for several important reasons: ethical principles such as respect for persons require investigators to facilitate informed consent (parental permission and assent) and appreciate factors that promote parents’ and children’s understanding of risks and benefits and informed, engaged research participation. The ethical principle of justice encourages investigators to develop methods to enhance research participation of minority and/or economically disadvantaged research participants who are underrepresented in research in pediatric psychology. To the extent that investigators implement research that facilitates diverse research participants’ informed engagement in research, this will enhance the quality of internal validity as well as the generalizability of data that are obtained.

Research on pediatric ethics will also illuminate important areas such as family communication and decision making, which are highly relevant to the management of pediatric chronic illness. Data from studies of ethics in pediatric psychology will also facilitate the training of researchers to enhance the quality of their interactions with research participants and improve the ethical conduct and methodological quality of their research. Finally, data from research on ethics in pediatric psychology can inform the decisions of institutional review boards (IRBs) concerning critical areas of research ethics such as parent and child experiences in research participation, perceptions of risk and benefits, and quality of consent. The extraordinary variation in pediatric IRB practice across settings, which is well documented (Kimberly, Hoehn, Feudtner, Nelson, & Schreiner, 2006), may be highly influenced by local practices, including experience with the types of research conducted in specific settings, and IRB membership composition. Valid and compelling data on important ethical issues provide generalizable scientific knowledge that can inform IRB practice and policy in specific areas of pediatric psychology research.

What are the types and functions of research on pediatric ethics? Kon’s (2009) conceptualization of different levels of research on bioethics provides a useful framework. The first category, descriptive or “lay of the land” research, defines current practices, opinions, beliefs, or decision making in a specific area of research or clinical care (Kon, 2009). Research on practices of payment to pediatric research participants (Weise, Smith, Maschake, & Copeland, 2002). In this volume, Birnie, Noll, Chambers, von Baeyer, and Fernandez’s description of researchers’ practices with the cold pressor test is an excellent example of this type of research. A second category, “ideal” versus “reality” research starts with an
assumption or premise concerning ethical norms and evaluates the extent to which research practice reflects this ideal. Research on parents’ understanding of information presented to them by investigators in clinical trials of pediatric cancer treatment falls into this category (Kodish et al., 2004). A third category of research ethics focuses on solving the problems that are raised by the ideal versus reality of research ethics. Research on improving the informed consent process (Tait, Koepel-Lewis, Malviya, & Philipson, 2005; Yap et al., 2009) falls into this category as does Kao’s research in this volume on methods enhancing research participation of minorities. Finally, the fourth category in Kon’s (2009) framework involves changing norms for research and/or standards of ethical practices based on the cumulative body of research that has been developed in these various areas.

The contributions to this special issue advance scientific knowledge and address practice and/or policy in the following important content areas: (a) description of researchers’ and families’ experience with specific research procedures (e.g., the cold pressor test that is widely used in research on pediatric pain) (Birnie et al., 2011), (b) recruitment of minority children and families in pediatric psychological research (Kao, 2011), (c) data collection with adolescents with human immunodeficiency virus (HIV) via the internet (Bull et al., 2011), (d) influences on parental decision making concerning research and participation in clinical care (Miller, Luce, & Nelson, 2011), and (e) child and adolescent participation in predictive genomic testing (Tarini, Tercyak, & Wilfond, 2011).

Researchers’ and Families’ Experience With Specific Research Procedures: The Example of the Cold Pressor Test

The cold pressor task (CPT), which requires a child to submerge his or her hand or forearm in cold water for as long as it can be tolerated (e.g., up to several min), is frequently used as an experimental method of inducing pain in pediatric research (von Baeyer, Piira, Chambers, Trapanotto, & Zelzer, 2005). This laboratory-based pain induction technique is a valuable method of reducing the impact of potential confounding variables and hence increasing the internal validity of pediatric pain research. Specific guidelines have been established concerning the ethically appropriate use of the CPT (e.g., when it is the sole valid means of obtaining critical information necessary to answer a scientifically relevant question; when no tissue or psychological trauma occurs; when a minimal amount of cold pressor stimulation is applied; and when the child can maintain control over the process by being able to remove his or her limb at any time) (Von Baeyer et al., 2005). However, up until now, data concerning research participants’ perceived acceptability and benefit of this procedure and researchers use of the CPT across a range of studies have not been available. However, such data are needed to inform researchers who conduct research using the CPT and IRBs who are called upon to determine the ethics of children’s participation in such research, which has no prospect of direct benefit.

Birnie and colleagues (2011) addressed this need by providing unique and valuable data on researchers’ use of specific procedures in applying the CPT (e.g., planned exposures in protocols, water temperature, maximum allowable time, and monitoring procedures) and parent and child perceptions of the best and least liked aspects of the CPT procedure. Not surprisingly, children and parents had different perspectives. For children, the best things about the experience included aspects of the protocol other than the CPT, compensation, and the task itself. In contrast, parents rated their interactions with researchers, their child’s enjoyment of research, and the opportunity to contribute to research/science most highly. With respect to least-liked aspects of the procedure, children disliked aspects of the protocol other than the CPT and the CPT task, whereas parents rated logistics (e.g., parking and scheduling) and answering questionnaires as least liked.

Birnie et al.’s (2011) findings also indicated substantial variation in setting-specific IRB practices concerning research that involved the CPT, which is consistent with other pediatric research protocols (Kimberly et al., 2006). The investigators sampled in this study reported that obtaining IRB approval for CPT studies was more difficult (19%), less difficult (19%), or comparable (63%) than other studies. Such variability is likely to reflect setting differences in local IRB practices and experiences with CPT protocols. A logical hypothesis is that IRBs who have not had previous experience with specific procedures or protocols would be more likely to raise concerns about the potential risks to participants. The cumulative experience of IRBs with specific protocols and procedures is quite variable and depends upon the research activities of investigators in specific settings. For this reason, data gathered by Birnie et al. (2011) that summarize the experience of 16 investigators’ across 41 studies that included 3000 participants and family participants with the CPT across a
range of settings are more generalizable than local experiences and thus can inform local IRB practices and policy.

One issue needs to be considered when interpreting Birnie et al.'s (2011) findings: the investigators did not query participants specifically about perceived risk versus benefit. Consequently, their findings do not map directly to IRB deliberations concerning evaluation of risk versus benefit as convincingly as they might have. This highlights the need for investigators to design studies and measures pertaining to research ethics in pediatric psychology so that they map as clearly as possible onto relevant ethical issues (e.g., perceived risk versus benefit) and principles (e.g., respect for autonomy and justice).

Enhancing Recruitment of Minority Families in Pediatric Psychology Research: Promoting Justice and External Validity

One of the essential ethical principles described in the Belmont Report is the principle of justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978), a cornerstone of which is equal access to research participation. Apart from ethical principles, access to research participation across broad segments of society is critical from the standpoint of enhancing external validity and generalizability of research in pediatric psychology, which is often based on convenience samples that are recruited from clinic settings (Drotar & Riekert, 2000). Findings from such populations are not necessarily generalizable across a broad range of demographics, races, and ethnicities. Unfortunately, minority children and families remain very much underrepresented in pediatric psychology research, despite the fact that they are an ever increasing population in the US (Mitchell, Patterson, & Boyd-Franklin, 2011).

Formidable barriers to participation of minority children, adolescents, and families in pediatric psychology research challenge investigators to develop and evaluate the efficacy of proactive strategies to enhance research participation of minorities (Huang & Coker, 2008). To address this need, Kao (2011) described the efficacy of strategies to enhance recruitment in Latino versus non-Latino families in a study of children with intellectual disability. The primary finding that active strategies of recruitment were more likely to enhance recruitment of minority families may generalize to other pediatric minority populations and underscore the efficacy of matching the recruitment strategy based on theory and clinical experience with the culture/ethnicity of research participants. Kao’s proactive recruitment strategy, which involved active, interpersonal, and direct contact with participants, was based on a collective orientation (e.g., in which family members are socialized to be sensitive to and accommodate the findings of others) (Triandis, 1994) and was most effective for families of Latino children. On the other hand, traditional advertisements were more effective for families of non-Latino children. The ethnicity-specific efficacy of these different recruitment strategies underscores the need for investigators to develop flexible approaches that are tailored to culture and ethnicities of participants in research in pediatric psychology. Kao’s (2011) findings are consistent with an emerging body of research that describes the importance of active engagement of investigators and use of multiple approaches to engage minority participants in research (Huang & Coker, 2008; Roosa, Liv, Torres, Gonzales, & Knight, 2008), including community participants (Brody et al., 2006) and collaboration with community organizations (Perri et al., 2008), churches (Resnicow, Taylor, Baskin, & McCarty, 2005), etc.

Another interesting and effective strategy that has been used by investigators to increase research participation and inform children and families about the nature of pediatric psychological research and potential options is Sickle Cell Research Day (Hines et al., 2011). This day-long activity brings children and adolescents with sickle cell disease, and their families together in a group in a structured, organized approach that includes meals, games, presentation of research findings, and the opportunity to participate in a specific, time-limited, 1-day research study during the meeting. This creative approach to engaging families in research has been shown to be successful, not only in recruiting families who are difficult to involve in both medical and psychological research, but also in re-engaging families who had been lost to medical follow-up in their child’s clinical care (Hines et al., 2011). Hines et al.’s (2011) approach also has the advantage of providing information about research and opportunities to participate in research in a nonthreatening context and maximizes opportunities created by social networks in the local African-American community.

The proactive recruitment strategies that were used by Kao (2011) and by Hines et al. (2011) are clearly more time consuming and costly than typical procedures. However, the ethical and scientific benefits of such procedures (e.g., reducing disparity and enhancing justice in research participation and enhancing generalizability of research findings) outweigh the costs. For this reason, it will be important for investigators to document the potential efficacy as well as time spent on proactive strategies in their research and include the costs in budgets for their research proposals. Moreover, additional research that demonstrates
the efficacy of proactive recruitment strategies across a wide range of cultures and ethnicities is needed.

**Data Collection in Pediatric Psychology Research via the Internet: Ethical Challenges of New Technology**

The extensive use of new internet technologies, including social media sites, has provided extraordinary opportunities for investigators in pediatric psychology to gather data but also raises challenging ethical issues. To address this need, Bull et al. (2011) describe their experiences with social media to promote healthy sexual behavior in youth at high risk for HIV. Their study was designed to compare changes in attitudes toward, norms for, and implementation of healthy sexual behavior among youth who were randomized to the JUST/U.S. study Facebook page compared to those who were assigned to a comparison Facebook page that offered news and current events. See Bull, Vallejos, and Ortiz (2008) and Levine, Madsen, Barar, Wright, & Bull (2011, manuscript under review) for more detail on study procedures.

Potential benefits of such research to youth at risk for HIV include an opportunity to interact with other youth online and obtain health information (Levine et al., in press; Livingstone, 2008). However, such benefits are balanced by potential risks to confidentiality. Bull and colleagues (2011) articulated the specific strategies that they used to reduce the risks to confidentiality of research participants, some of which are applicable to internet research with other high-risk pediatric populations. For example, to help preserve their confidentiality, youth were asked to ‘like,’ that is approve of their participation in the intervention or control page. In addition, investigators had no access to personal information concerning participants’ profiles and all assessments were collected through a secure internet site that was not housed on Facebook.

It is also important to note that Bull et al.’s (2011) study had a Facebook page that was open to participants’ postings. For this reason, confidentiality regarding participants’ specific posts and comments did not exist. To address this issue, as a safeguard, the investigators developed posting etiquette or guideline protocols that were shared with participants, monitored their study site multiple times each day to identify incorrect or potentially confusing information, and removed any postings that they judged to be offensive, misleading, incorrect, or inflammatory. Surprisingly, such postings did not occur, perhaps owing to the investigators’ close, proactive attention to these issues.

Bull et al.’s (2011) valuable suggestions should be helpful to the increasing number of researchers who will be conducting research via social media and technologies such as cell and smartphones. The field of pediatric psychology is only beginning to consider the ethical issues that arise in social media research with children and adolescents. For this reason, future studies of the ethical issues including the risks/benefits of such research and research participants’ understanding of such critical issues would be very instructive.

**Influences on Parental Decision Making Concerning Research Participation and Clinical Care**

Miller et al. (2011) identified relevant external influences that relate to distress experienced by parents of children with a life-threatening illness in the process of making decisions about their child’s participation in research and clinical care. Higher levels of perceived external influences from other individuals (e.g., physician, spouse, other family members, etc.) were associated with parental distress (Miller et al., 2011). Moreover, parents’ experience of greater external influence was associated with higher distress, including uncertain, confused, and hostile feelings when their decision making preference was low and task-focused coping was high. Miller et al.’s (2011) findings underscore the need for investigators to consider individual difference variables such as coping style and decision making preferences that may influence parental distress in decision making in research and clinical care.

The authors’ inclusion of subsamples of parents who made decisions about enrolling in a research protocol and those who made decisions about protocol-based clinical treatments was unique. The rationale for this strategy was that the different decisions made by these two samples of parents involved common features (e.g., interventions for life-threatening illness, uncertainty, time pressure, emotional intensity, and complex information). Differences between research-related versus clinical decisions include the nature of parents’ relationships with practitioners versus investigators who obtained consent. Exploratory analyses suggested that the pattern of findings was comparable for research and treatment-related decisions. However, it will be important for researchers to replicate Miller et al.’s (2011) findings and in the process provide a comprehensive description of the specific features of research protocols and nonresearch-related decisions. Such description would allow examination of the unique attributes of protocols or treatments that affect parental
distress and perceptions of autonomy as well as effects that generalize across protocols.

Miller et al.’s (2011) cross-sectional design made it difficult to identify the specific direction of effects (e.g., parental distress may have influenced perceptions of external influence rather the other way around). For this reason, prospective research is necessary to characterize specific influences on parental decision making. For example, it is very possible that parents’ experience of emotional distress in decision making changes over time in clinically relevant ways. For example, distress experienced by parents at the time they are called upon to make a difficult decision concerning research participation or clinical treatment might affect the quality of informed consent whereas a high level of postdecision emotional distress may affect the quality of their lives for some time to come.

Miller et al. (2011) made several cogent recommendations to investigators to reduce the level of parental distress and enhance the quality of their decision making by providing opportunities for parents to discuss their experience of their decision making process, including their perceptions of external influences. Researchers and practitioners might also wish to use valid measures of distress and voluntariness (Miller et al., 2009) to monitor the process and outcomes of parental decision making in research and clinical care.

New Frontiers of Research: Predictive Genomic Testing with Children and Adolescents

In their commentary, Tarini et al. (2011) describe the potential importance of child and adolescent participation in predictive genomic testing, which is a new research frontier. These authors reviewed developments in research and clinical care in genomic testing such as testing for risk for breast cancer, including advent of genomic technologies that provide data concerning future health risks that may have important implications for preventive health actions (Feero, Guttmancher, & Collins, 2010). At the same time, concerns have been raised about the potential for faulty, misleading data generated from genetic testing (Hamburg & Collins, 2010) as well as increased psychological distress due to knowledge of one’s genetic disposition. Studies of testing for genetic risk have focused on adults. However, some parents also have expressed interest in predictive genomic testing for their children and raised questions about the potential benefits of such testing (Tarini et al., 2011). Although professional organizations, including the American Academy of Pediatrics, have discouraged genetic testing in children for the detection of adult onset diseases (Nelson, Botkin, Kodish, Levettown, Truman, & Wilfond, 2001), Tarini et al. (2011) present an alternative view: they raise the possibility that genetic testing in children could have positive health consequences in specific situations by providing additional motivation for lifestyle modification in children at risk (e.g., obese children who have elevated genetic risk for developing type 2 diabetes; adolescents with attention deficit hyperactivity disorder who are at elevated genetic risk for smoking). Tarini et al.’s (2011) primary recommendation was that additional research is very much needed to determine the benefits and risks to inform clinical application of genetic testing in children and add to a limited database that thus far has not identified significant psychological impact of this procedure (Wade, Wilford, & McBride [2010] for a review). Evaluations of the impact of genetic testing on children’s wellbeing as well as the effectiveness of genetic testing on the success of children’s lifestyle modifications and prevention of unhealthy behavior in children and adolescents who are at elevated genetic risk were reviewed as relevant new frontiers of research in pediatric psychology (Tarini et al., 2011).

In her commentary, Patenaude (2011) presented a very different view on the desirability of direct consumer genetic testing in children. She noted that children’s participation in direct to consumer genetic testing would expose them to data with highly variable accuracy and predictive validity. Moreover, she expressed concern that childrens’ participation in genetic testing would deprive children of their autonomous right to decide as adults whether or not to learn about their genetic results. Moreover, she underscored the lack of data concerning the psychological impact of such testing on children and recommended a medical expertise to help children and families weigh the benefits of testing for a large number of genetic conditions. On the other hand, Patenaude (2011) did note that research on genetic testing would be useful in conditions such as Li–Fraumeni Syndrome where new screening techniques suggest that all at risk children should receive genetic testing early in life (Villani et al., 2011). Finally, Patenaude (2011) highlighted the need for additional pediatric psychology research to provide data that inform families about the risks, benefits, and limitations of genetic testing in children.

Future Directions

Taken together, the authors’ collective contributions to this special issue have given readers a great deal of food for thought concerning relevant research questions and
promising new directions for future research on ethics in pediatric psychology. Extending the body of descriptive and intervention research concerning the ethics of pediatric psychology research will not only inform work of investigators but IRBs’ reviews and implementation of regulatory considerations. Such research efforts would be informed by objective and valid measurement of key ethical issues such as perceptions of risks versus benefits (Jeste et al., 2007), competence and decisional capacity (Appelbaum & Grisso, 2001; Sturman, 2005), voluntariness and decision making control (Miller et al., 2009), and the quality of parent or child understanding of research (Kodish et al., 2004), including the therapeutic misconception (Appelbaum et al., 2004). Routine inclusion of valid measures of key benchmarks of the quality of parental permission, assent, and decision making in ongoing research would give investigators important information concerning the quality and impact of their consent procedures and allow them to identify areas (e.g., misperceptions of risk or benefit) that need to be addressed in consent procedures and recruitment (Huntington & Robinson, 2007).

Obtaining ongoing feedback from research participants concerning their reactions to participation, understanding of psychological research, and ongoing education of participants are important for all pediatric populations but may have special benefit for populations who mistrust or misunderstand research procedures. Moreover, a critical area for future research on ethics in pediatric psychology concerns the development and evaluation of interventions to improve parent and child understanding of research, reduce misconceptions, and otherwise empower participants to make informed decisions concerning research participation. One option for such interventions would involve training investigators to improve the quality of their communications with parents and children in making difficult, research-related decisions and parental understanding of the risks and benefits of their children’s research participation in research (Yap et al., 2009). Studies that provide data on hypothetical or simulated research-related decisions provide another alternative for research design (Brody et al., 2003). Testing the efficacy of alternative educational methods such as videos and Internet-based tools in improving parents’ participation in and understanding of research is another important option for intervention research (Hazen et al., 2010).

The research that is described by the authors in this volume raises a number of important challenges related to the design and measurement as well as implementation. It is very difficult to conduct studies of research ethics, whether they are analog studies, observational studies of the process of consent and research participation, or interventions to promote more optimal research participation.

Researchers will need resources to conduct research on the ethics of pediatric psychology research. The National Institutes of Health has an active program announcement to fund research on ethical issues in biomedical, social, and behavioral research on projects that analyze and address ethical challenges and issues related to the conduct of biomedical, clinical, and social research. Topics relevant for this program include ethical consideration of new and emerging technologies, study design issues, therapeutic misconception, research on vulnerable populations and urgent situations, dissemination of research findings, and oversight of research (http://grants.nih.gov/grantsguide/pa_files/pa-11-180.html). As demonstrated by the contributions to this special issue, pediatric psychologists have an important role to play in the developing the science of the ethical conduct of research. The Journal of Pediatric Psychology welcomes the submission of manuscripts in this important area.

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References


