Published in final edited form as:
J Pediatr Health Care. 2010 ; 24(1): 66. doi:10.1016/j.pedhc.2009.08.011.

Protection of Children in Research

Rita H. Pickler, PhD, RN, PNP-BC, FAAN and
Professor, Family and Community Health Nursing, Acting Associate Dean for Research and Scholarship, School of Nursing, Virginia Commonwealth University, 1100 E. Leigh Street, Box 980567, Richmond, VA 23298-0567, rpickler@vcu.edu

Alison T. Martin, MS, RN, CPNP
Newborn and Pediatric Intensive Care Unit Care Coordinator, Department of Care Coordination, Virginia Commonwealth University Medical Center, 401 North 12th Street, Box 980104, Richmond, VA 23298-0104, amartin2@mcvh-vcu.edu

In this issue of the *Journal of Pediatric Health Care*, the National Association of Pediatric Nurse Practitioners (NAPNAP) has published its revised Position Statement on Protection of Children Involved in Research Studies. That document presents what NAPNAP and many other organizations consider acceptable practices for researchers who are designing, implementing, or otherwise participating in research studies that involve children. This column will focus on some of the particularly difficult issues associated with recruiting and consenting young children to research studies, areas of concern that the position statement also addresses. Examples from our own experiences in a study of preterm infants will be used to illustrate some of the issues and potential solutions.

Recruiting and Consenting in a Study of Preterm Infants

Nursing research generally requires human subjects. Consequently, an essential element of research is the recruitment and consent of participants. Good planning is indispensable to the process of recruitment and consent. Planning includes an appropriate sampling plan with well defined sampling procedures. In addition, good planning entails knowing the characteristics of the particular target population as well as knowing the accessibility potential participants in the research setting; researchers need to know who and where and when to recruit. Researchers need also to be sure that participants understand what they are consenting to and what the benefits of the research are to them. Considering issues of recruitment and consent as part of a continuum may help researchers to conduct research in both an ethical and efficient manner.

Moreover, today's institutional review boards (IRBs) as well as funding agencies are increasingly concerned with protecting the rights of human subjects. Recent federal policies for grant review suggest more careful scrutiny of investigator plans for recruitment of subjects, particularly in regard to the appropriate inclusion of minorities in research studies, an important human rights consideration. For example, the representation of minority children in research studies is important and both under- or over-representation of minorities may create bias and lead to research findings that are of questionable applicability. Thus, while there is an over-representation of black/African American children in all types of studies, and especially in

Neither Rita Pickler nor Alison Martin report financial interests nor potential conflicts of interest.

Phase III clinical trials and in studies classified as potentially stigmatizing, Hispanic children remain under-represented in almost all types of research, perhaps because of language difficulties or maybe because they are undercounted. White children are also under-represented in research except in non-therapeutic studies (Walsh & Ross, 2003).

Recruiting children, in our case, preterm infants, who are considered members of a vulnerable population into research, requires careful thought and planning. In the case of participation of very young children in research, it is the child's parents who are actually recruited and who give consent for the child's participation. In making consent decisions on behalf of their preterm infants in our study, parents were influenced by risk and benefit assessments, attitudes toward research, and the integrity of the consent process. Illness severity, often a concern of parents of very fragile preterm infants, or sociodemographic characteristics, often cited as a barrier to research consent (Tait, Voepel-Lewis, & Malviya, 2003), did not seem to be a factor in parent's willingness to consent. Many of the infants enrolled in the study had been very ill and were at high risk for continuing health problems. Also, perhaps because of the demographics of our particular institution, the majority of our participants came from disadvantaged socioeconomic and minority groups.

Benefits to Research

Participation in research can be of benefit to the participant. However, sometimes there is no direct benefit. That was the case with our study of feeding readiness in preterm infants (Pickler, Best, Reyna, Wetzel, & Gutcher, 2005). And yet, of parents who were approached about enrollment in our study, 97% consented to their infants' participation. While we did not systematically obtain information about why parents agreed to allow participation in the study, parents often stated that they consented to participation in the hope that the study findings would be of help to future preterm infants. This is similar to reasons cited in the literature for parental consent for their children's involvement in research – that is, altruistic reasons motivated parents' decisions (Rothmier, Lasley, & Shapiro, 2003). We did offer small "incentives" to parents – a gift card to a local store – in appreciation for the infant's participation. Yet, parents often forget that the incentive had been promised to them and many stated that the gift card was not an incentive over their desire that other children might benefit from the research. Again, this is consistent with what little research exists on incentives, which notes that financial gain does not serve as a motivator for many who chose to participate in research (Ulrich, & Grady, 2004).

Attitudes about Research

It is important to note that not only are parents altruistic, they are human. Parents will respond to the environment pretty much as expected. That is, if pushed or if they perceive coercion, they will not consent. Rather, the environment in which consent is obtained influences parental decision making (Stokowski, 2004). In addition, even though parents are signing consent forms on behalf of their children, they are also thinking about themselves. They want to learn about their children (Rothmier, et al., 2003). This was true in our study as many parents reported to us at their infant's follow-up visit that they learned how to feed their baby because the baby had participated in the study. Teaching parents was not a goal of the research. However, parents cited their own learning as a benefit, even though we did not. This acknowledgement of an "educational benefit" provides insight into what parents may be thinking when they consent.

Consent Process

Parents often have fears that research study participation could be detrimental to their child. Full disclosure of what will happen during the research and what is expected of the research participant is essential during the recruitment and consent process to help allay these fears. Full disclosure is in fact, the cornerstone for informed consent; most patients who are being recruited

for a clinical trial say need needed more, not less information to make a reasoned decision about participation (Ferguson, 2002). In our study, we provided both written and verbal information to parents. Written information conveyed on the consent form, which parents received a copy of, and also in an information brochure with additional information to help parents understand the study's purpose. We verbally reviewed the study consent form and the information brochure with parents and encouraged them to ask questions. Because we were using a computerized data collection system for physiological data, we also showed parents the research equipment during the consent meeting. We used a premie-sized doll to show how data collection devices would be placed and allowed parents to handle the research equipment. This hands-on opportunity was a helpful and easily implemented strategy to alleviate concern about equipment.

We also found that scheduling appointments with parents to discuss the study and then scheduling a second appointment to sign the consent forms worked well to meet parents' needs. One advantage we had was that we did not generally need to recruit for the study immediately after the preterm infant's birth. Thus, we had time to meet families of potential participants before the need to obtain consent. In addition, scheduling appointments meant that we did not interrupt parents' visits to their infant and conveyed respect for that important time. Parents also had an opportunity to mentally prepare for a scheduled meeting.

In all cases, we attempted to provide a relaxed, unhurried environment for discussion of the study and the consent process. At the time, our neonatal intensive care unit consisted of two large rooms each with about 20 incubators. This environment offered little privacy for discussion and so, whenever possible, we used the unit's family or conference rooms. In these more quiet places, mothers appeared to be less inhibited about expressing their thoughts and concerns. In addition, because as the researchers we did not have concurrent patient care responsibilities, we were able to focus attention to the mother and her needs. Since parents' ability to listen to and hear the researcher is related to parents' understanding of the research, this approach aided our success at recruitment.

The research setting can enhance or diminish the success of the consent process. The researcher must develop a strong foundation of research education among health care members before approaching participants to discuss consent. When informed, the health care team will be more likely to support the research activity in the clinical setting. The collaboration between researchers and clinicians enriches the research environment and at the same time likely leads to greater research participation (Thompson, Pickler, & Reyna, 2005).

We found that many things influenced the consent process, including changes in the infant's physical status, the mother's emotional state, and unit dynamics. Thus, although we scheduled consent appointments in advance, we often had to reschedule those appointments. In the case of worsening health status of the baby, we often, by protocol, had to reschedule the consent appointment in order to ensure that it would be safe for the infant to participate in the study. At other times, we had to inform the parents that because of the infant's health status, he or she was no longer eligible to participate in the study. At the same time, we also recognized that mothers usually needed more time in these situations to work through their own anxieties about their infants. As neonatal intensive care nurses, we were aware that mothers needed support during these times as well in addition to guidance from care providers.

Conclusion

Obtaining informed consent is a skilled process and a time consuming one. When meeting with parents, the researcher is obligated to present the study with clarity (Ferguson, 2002). The consent process is one of education. Participants, or in our case, parents, need to understand

what they are being asked to consent to. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subjects. Fortunately, increasingly more resources now exist for both researchers and parents. A particularly useful resource can be found on the National Institute of Health's website (http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php). Since many children who participate in research studies are already diagnosed with a health condition, this site provides both information and reassurance to parents. However, this general information, while excellent and likely to encourage parents to allow their child to participate in research, will never take the place of a researcher's own well-developed plan for recruitment and consent.

Acknowledgments

This work was supported in part by grant R01 NR005182, from the National Institute of Nursing Research, National Institutes of Health.

References

Ferguson PR. Patients' perceptions of information provided in clinical trials. Journal of Medical Ethics 2002;28:45–48. [PubMed: 11834760]

Pickler RH, Best AM, Reyna BA, Wetzel PA, Gutcher GR. Prediction of feeding performance in preterm infants. Newborn and Infant Nursing Reviews 2005;5:116–123. [PubMed: 16467910]

Rothmier JD, Lasley MV, Shapiro GG. Factors influencing parental consent in pediatric clinical research. Pediatrics 2003;111:1037–1041. [PubMed: 12728085]

Stokowski LA. The validity of informed consent for neonatal research. Advances in Neonatal Care 2004;4 (5):256.

Tait A, Voepel-Lewis T, Malviya S. Participation of children in clinical research: factors that influence a parent's decision to consent. Anesthesiology 2003;99:819–825. [PubMed: 14508312]

Thompson A, Pickler RH, Reyna BA. Clinical coordination of research. Applied Nursing Research 2005;18:102–105. [PubMed: 15991108]

Ulrich C, Grady C. Financial incentives and response rates in nursing research. Nursing Research 2004;53:73–74. [PubMed: 15084990]

Walsh C, Ross LF. Are minority children under- or overrepresented in pediatric research? Pediatrics 2003;112:890–895. [PubMed: 14523182]