NAPNAP Position Statement on Protection of Children Involved in Research Studies

Practitioners must be involved in research in order to provide quality health care and evidence-based practice to all pediatric clients in an ever-changing practice environment. This allows best practice standards to be established for all parameters of pediatric health care, including assessment, diagnosis, management, and evaluation of care. Evidence-based practice has the potential for significant improvements in pediatric health care. Practice improvements and changes occur when research is actively pursued, evaluated, and applied to clinical assessment and decisions. The National Association of Pediatric Nurse Practitioners (NAPNAP) acknowledges the need for evidence-based practice in the clinical setting and its dependence on continuing research, including research involving children.

Pediatric health care providers need to be cognizant of the safety, privacy, and ethical issues involved in conducting or participating as clinical investigators in all areas of pediatric research. Health care research involving children involves specific ethical criteria that must be considered by parents and/or legal guardians (Institute of Medicine, 2004). Children are a vulnerable population and must receive added protection with regard to confidentiality and exposure to undue risk (American Academy of Pediatrics [AAP], 1995a; Iltis, Wall, Lesandrini, Rangel, & Chibnall, 2009). There are unique issues related to consent and assent in pediatric research. Informed consent must be obtained from the parent or guardian, with the understanding that they are acting in the best interest of the child, and assent is given by the child who is of sufficient maturity and capacity to indicate his or her agreement to participate (AAP, 1995a; Albert Einstein College of Medicine, 2003; Koelch et al., 2009; Lindeke, Hauck, & Tanner, 2000).

The Code of Federal Regulations (Department of Health and Human Services [DHHS], 2005) states that the decision to obtain assent from a child depends on age, maturity, and psychological state. Consent should be given only after a clear and understandable explanation of the study purpose, procedures, and risks/benefits of participation have been reviewed, with provision of medical translation services as necessary. It should be clearly stated that participation in the research is voluntary and that non-participation in or subsequent withdrawal from the research will not affect the care and treat that the child would otherwise have received. Adequate time must be allowed for the child and family to ask questions about the research and to receive answers prior to obtaining assent from the child and consent from the parent or legal guardian. Pediatric nurse practitioners (PNPs) serve as advocates for families considering participating in a research study by ensuring that adequate information is provided regarding the risk/benefit ratio of the study and that ongoing monitoring occurs throughout the study such that risks or adverse events are identified as quickly as possible. PNPs should encourage parents to pose questions about research participation including questions about participant obligations, foreseeable adverse events, history of related trials, safety provisions, and potential outcomes. PNPs should be aware that notification of the progression of study, untoward adverse events associated with participation in the study, and final results must be communicated to all study participants on an ongoing basis.

Studies should be designed in such a way as to enhance the potential benefits to the child and family and minimize the potential risks. Risks for children involved in research are unique and may include physical

Adopted by the National Association of Pediatric Nurse Practitioners' Executive Board on June 27, 2009.

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J Pediatr Health Care. (2010) *24*, 17A-18A.

0891-5245/$36.00

doi:10.1016/j.pedhc.2009.08.012

or psychological harm, pain, discomfort, and anxiety to the child and/or the family. The child's level of development, relationship to caregivers, and previous experience in the health care environment must be considered when planning research. Special populations of children, such as children with chronic or terminal illness, children with special health care needs, and children with disabilities, need extra protection.

All research studies involving children should be reviewed and approved by an Institutional Review Board (IRB) that protects the rights and welfare of children and families who take part in research. The IRB should ensure that ethical principles governing the protection of research participants as well as federal regulations, state law, and local institutional policy are applied to research activities.

Children should enjoy equal access to existing as well as new therapeutic agents and be included in formal clinical pharmaceutical studies when the drug offers potential benefits to them (AAP, 1995b). In most cases, studies involving children should be preceded by adult clinical trials to provide preliminary pharmacokinetic, safety, and efficacy data. In some instances, drugs and interventions intended to treat specific diseases that primarily or exclusively occur in children may be studied initially in children.

NAPNAP acknowledges the need for evidence-based practice in the clinical setting and recognizes that continuing research, including research involving children, will be required to gather that evidence. Therefore, NAPNAP advocates for:

1. Research not involving greater than minimal risk to the child; or if the research involves greater than minimal risk, then it must have the prospect of direct benefit to the child. Other circumstances in which greater than minimal risk may be considered are those in which the standard treatments are known to have poor outcomes and the information gained would contribute to improved care to the population under study and/or generalizable knowledge.
2. Evidence-based research that enhances the empirical foundation of the care provided to children and their families.
3. Protection of confidentiality and privacy throughout all research activities.
4. Appropriate use of assent documents for children unable to give informed consent and consent documents for their parents and for consent documents for both the child and parent when the child is developmentally ready to provide informed consent (Kon, 2006).
5. Research protocols that are based on rigorous designs suitable to address the question under study.
6. Research that is planned and conducted in a manner most likely to achieve valid and generalizable knowledge in a cost-effective way.
7. Research studies involving children that take place in an environment that provides for the ethical treatment of children and the physical, emotional, and psychological safety of the child and the family.
8. Research guided by the ethical principles of: respect for person, beneficence, and justice (U.S. Department of Health, Education, and Welfare, 1979).
9. Ongoing continuing education on research utilization for all pediatric health care providers.
10. Research that recognizes, respects, and considers cultural differences and the special needs that these differences may require.

NAPNAP strives to support the quest for improved care through research and to assist members in participation in research protocols. Research is essential to advance knowledge about children's health and development. Research involving children should be based on sound scientific concepts and should pose questions of importance to children and families.

The National Association of Pediatric Nurse Practitioners would like to acknowledge the contribution of the NAPNAP Research Committee to the development of this statement.

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