

Protection of Children Involved in Research Studies

Practitioners must become 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 research 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 Nurse Practitioners (PNPs) 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 ([Society for Research in Child Development, 1990](#)). Children are a vulnerable population and must receive added protection with regard to confidentiality and exposure to undue risk ([AAP, 1995a](#)). 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 from the child when the child is of sufficient maturity and capacity to give consent ([AAP, 1995a](#); [Lindeke, Hauck & Tanner, 2000](#); [Albert Einstein College of Medicine, 2003](#)). The Code of Federal Regulations ([DHHS, 2001](#)) 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, pro-

cedures, 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 treatment 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. PNPs of families participating in research are advocates for the family ensuring adequate sources of information prior to consent and monitoring during their research participation. 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.

All research designs must attempt to have the potential benefits to the child and the family outweigh the potential risks. Risks in children are unique and include physical, psychological, and emotional 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. Additionally, researchers should have access to an Ethics Committee, which includes members with experience in or knowledge of children and child development, whenever there are potential ethical concerns. Ethics Committees have a responsibility to advocate for the interests and needs of children.

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 in children should be preceded by adult clinical trials to provide preliminary pharmacokinetic, safety, and efficacy data. In some instances, drugs intended to treat specific diseases that primarily or exclusively occur in children may be studied initially in children.

The National Association of Pediatric Nurse Practitioners (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 where minimal risk to the child is involved, potential benefits outweigh risk or in the special circumstance where the patient outcome is predetermined to be poor, the information gained would contribute to improved care to the population under study and/or gener-

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- alizable knowledge to implement care of children.
2. Evidence-based research to enhance evidence-based practice by all pediatric health care providers.
 3. Protection of confidentiality and privacy throughout all research activities.
 4. Research that recognizes, respects, and considers cultural differences and the special needs that these differences may require.
 5. Research protocols that are founded on "sound science" and will answer the question under study.
 6. Research that is planned and conducted in a manner most likely to achieve a valid and successful conclusion 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 (DHEW, 1979).

9. Ongoing continuing education for all pediatric health care providers in the area of pediatric research and its application.

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.

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REFERENCES

- Albert Einstein College of Medicine (2003). Enrollment of Minors in Research: Principles and Guidelines. New York, NY: Author. Retrieved September 8, 2003 from http://www.aecom.yu.edu/home/CCI/enrollment_of_minors_in_research.htm.
- American Academy of Pediatrics (1995a). Informed consent, parental permission, and as-

sent in pediatric practice (RE 9510). *Pediatrics*, 95: 314-7.

American Academy of Pediatrics (1995b). Guidelines for the ethical conduct of studies to evaluate drugs in pediatric populations. *Pediatrics*, 95: 286-94.

Department of Health and Human Services National Institutes Health Office for Protections from Research Risks. (2001). *Code of federal regulations*. Retrieved September 8, 2003 from <http://ohrp.osophs.dhhs.gov/humansubjects.guidance/45cfr46.htm>.

Lindeke, L.L., Hauck, M.R., & Tanner, M. (2000). Practical issues in obtaining child assent for research. *Journal of Pediatric Nursing*, 15: 99-104.

Society for Research in Child Development. (1990). Ethical standards for research with children. Retrieved September 8, 2003 from <http://www.srccd.org>.

U.S. Department of Health, Education, and Welfare (1979). The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Retrieved December 5, 2003 from <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>.

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