

Ambulatory Pediatric Association Policy Statement

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Ensuring Integrity for Research With Children

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ABSTRACT

Conflicts of interest (both financial and nonfinancial) have eroded public trust in medical research. There is now overwhelming evidence for systematic bias due to conflicts of interest associated with financial links between researchers and their institutions to commercial entities. To help manage and eliminate conflicts of interest and to regain public trust, the Ambulatory Pediatric Association developed a code of ethics for research in general pediatrics. While researchers in general pediatrics encounter many of the same ethical challenges as other medical researchers, many issues apply uniquely to the study of children's health because children may not be able to protect their own interests.

Background

The Ambulatory Pediatric Association (APA) believes those engaged in research in general pediatrics deserve guidance in addressing ethical challenges to integrity in the conduct of research, including actual or perceived conflicts of interest. In disseminating this statement of ethical principles, the APA joins other organizations which are taking a public stand on research integrity.¹ The American College of Physicians-American Society of Internal Medicine, in conjunction with the European Federation of Internal Medicine and the American Board of Internal Medicine, recently published a Charter on Medical Professionalism² and position papers on physician-industry relations that offer recommendations to individual physicians³ and to medical professional societies.⁴ The Society for Adolescent Medicine has developed a code of research ethics⁵ and the American Public Health Association

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has promulgated a Public Health Code of Ethics.⁶ The International Society for Environmental Epidemiology has drafted a set of ethics guidelines for professionals in environmental epidemiology.⁷

The Ambulatory Pediatric Association is the primary professional organization for academic researchers, educators, and community practitioners who are involved in research and education in general pediatrics. As such, the APA is well positioned to promote research integrity in pediatrics. Although the ethical principles for pediatric research resemble those developed for related disciplines, it is especially important that research with children adhere to these guidelines, because children, unlike adults, may not be able to protect their own interests. A code of ethics for research in general pediatrics can serve as a guide to both new and seasoned investigators.

The APA Research Committee first discussed this issue on May 4, 2002, and agreed to undertake the development of a workshop on Conflict of Interest in Pediatric Research at the 2003 meeting of the Pediatric Academic Societies. Funding for APA activities to enhance research integrity was supported through a cooperative agreement with the Association of American Medical Colleges. Under this agreement, an invited group of pediatric generalists met in December 2003 and prepared a draft code of ethics for research in general pediatrics. An open discussion of the draft code was held at the May 2004 meeting of the Pediatric Academic Societies. Additional contributions have resulted in this policy statement, which was approved by the APA Board of Directors on August 20, 2004.

CODE OF ETHICS FOR RESEARCH IN GENERAL PEDIATRICS

In meeting its responsibility to research subjects and to the profession of pediatrics, the Ambulatory Pediatric Association has created this code to highlight important ethical issues in research, to serve as a guide for its members, to facilitate self-scrutiny, and to shape future debate. While researchers in general pediatrics face many of the same ethical challenges and pitfalls encountered by other researchers, many issues apply uniquely to the study of health and health care of children and families.

TRUTH IN RESEARCH

Investigators should pursue truth aggressively and present their findings accurately, fairly, and impartially, placing primary value on clinical significance and relevance.

Investigators should:

- Continuously seek the truth.
- Design studies with adequate power and methods appropriate to reach meaningful conclusions.
- Describe the methods of the study in any publication
- Use caution in generalizing beyond the study population.
- Clearly identify study limitations.
- Write an abstract that reflects the content and tone of the full document.
- Include as authors all those who made substantial contributions to the work reported in the manuscript.
- Clearly indicate specific contributions of all authors.
- Disclose to the journal, reviewers, and the public any affiliations of authors with entities that might have a direct or indirect financial interest in the content of a publication.
- Strive to ensure fair, public, and dispassionate scientific review.

Investigators should not:

- Publish anything known to be false.
- Fail to disclose data on adverse reactions or side-effects.
- Include as authors anyone who did not make a substantial contribution to the work reported in the manuscript.
- Manipulate data to mislead research sponsors, clinicians, families, policymakers, members of the press, or the general public.
- Plagiarize.

RESPECT FOR PERSONS

Investigators should respect the dignity of individuals and communities.

Investigators and their institutions should:

- Respect human research participants and abide by ethical and legal protections for subjects,⁸ including obtaining approval by appropriate bodies (e.g. Institutional Review Boards) prior to implementing studies and before changing study procedures.
- Take into account the unique circumstances of children enrolled as research participants, ensuring protection for their particular vulnerabilities by 1) carefully determining that potential benefits outweigh risks, 2) appropriately involving children in the decision to enroll them as subjects, and 3) assuring that all procedures maximize children's physical safety and psychological well being.
- Request assent from children whenever reasonable^{9,10}
- Apply the concepts of "minimal risk," and "direct benefit for the individual child," and "minor increase over minimal risk," and follow the guidelines for special protections for children as research subjects defined by the Office of Human Research Protections of the Department of Health and Human Services.¹¹
- Respect the privacy and confidentiality of study participants and their families.

- Treat other study investigators with respect and dignity.
- Respect novel and controversial findings.
- Respect the right to investigate any hypothesis that may enhance the well being of children, no matter how unpopular.

Investigators and their institutions should not:

- Personally attack or try to undermine competitors in the field.
- Knowingly place children and their families at undue risk.
- Treat colleagues, children, and their families in an uncaring, hostile manner.

PRESERVING INDEPENDENCE OF RESEARCHERS AND STUDY FINDINGS

Investigators should pursue scientific questions independent of biasing influences, avoiding real or perceived conflicts of interest. Pediatric investigators should defend the independence of all investigators from those seeking control over study results or their dissemination.

Investigators should:

- Identify all sources of funding in manuscripts, abstracts, and public presentations.
- Identify sources of funding to potential study participants.
- Disseminate the preliminary findings of other investigators only with permission.
- Collect and analyze data and report findings without fear or favor and vigorously resist undue influence from any outside forces, including funding sources and special interest groups.
- Resist those who seek to buy or politically influence study findings or their interpretation or who seek to intimidate those who design, analyze or report results.
- Resist self-interest or peer pressure that might erode scientific integrity, the safety of research subjects, or service to the public.
- Defend the rights of all investigators, resisting institutional restrictions of any investigator's field of inquiry.

Investigators should not:

- Accept gifts, favors, or compensation from those who might influence study design or analysis.
- Engage in contractual or other arrangements that allow funding sources to alter data, bias analysis of results, or interfere with the dissemination of findings.
- Engage in activities that may compromise their independence.

MAINTAINING INVESTIGATOR ACCOUNTABILITY

Investigators and institutions are accountable for their actions to research subjects, the public, the profession, and themselves.

Investigators and institutions should:

- Actively encourage adherence to these standards by all investigators.

- Respond to public concerns.
- Investigate complaints and correct problems promptly.
- Explain scientific processes to the public, especially when results spark questions or controversy.
- Carefully listen to investigators who raise ethical objections.
- Create environments that support and encourage discussions of ethical issues in research.
- Support rigorous ethics training for new and established investigators and research team members.
- Take responsibility for data and conclusions published under one's name.

Investigators and institutions should not:

- Order or encourage employees to commit any unethical act.

STRIVING FOR EXCELLENCE

Investigators should pursue excellence in research design, implementation, and reporting.

Investigators should:

- Take the earliest possible opportunity to subject innovative ideas to systematic research.
- Use methods and wording with skill and thoughtfulness, avoiding techniques that skew or distort findings.

Investigators should not:

- Pursue frivolous hypotheses.
- Publish multiple small findings in different journal articles to exploit the "least publishable unit."

ACHIEVING JUSTICE

Investigators should seek fair distribution of research benefits and burdens among relevant populations of potential subjects.

Investigators should:

- Recognize that children, their families, and particular subpopulations (e.g., ethnic, economic, religious groups) may be vulnerable to exploitation, coercion, or manipulation and should take steps to prevent such abuses.
- Offer research opportunities to all families and children without regard to ethnicity, gender, sexual orientation, income or religion.
- Encourage community participation in the design and implementation of research projects.

Investigators should not:

- Place excessive burdens on any group or community.
- Exploit the most vulnerable children, such as those with disabilities or social disadvantage.
- Inappropriately exclude children from being studied if studies could provide useful information about children's health.

Ambulatory Pediatric Association Research Committee (2003–2004)

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REFERENCES

1. Association of American Medical Colleges. *Developing a Code of Ethics in Research: A Guide for Scientific Societies*. Washington, DC; 1998.
2. ABIM Foundation, ACP—ASIM Foundation, European Federation of Internal Medicine. Medical professionalism in the new millennium: a physician charter. *Ann Intern Med*. 2002;136:243–246.
3. Coyle SL, Ethics and Human Right Committee, American College of Physicians—American Society of Internal Medicine. Physician—industry relations. Part 1: individual physicians. *Ann Intern Med*. 2002;136:396–402.
4. Coyle SL, Ethics and Human Right Committee, American College of Physicians—American Society of Internal Medicine. Physician—industry relations. Part 2: organizational issues. *Ann Intern Med*. 2002;136:403–406.
5. Society for Adolescent Medicine. Code of Research Ethics. A position paper of the Society for Adolescent Medicine. *J Adolesc Health*. 1999;24:277–282. Available at: http://www.adolescenthealth.org/html/code_of_research_ethics.html. Accessed November 2, 2004.
6. Thomas JC, Sage M, Dillenberg J, Guillory VJ. A code of ethics for public health. *Am J Public Health*. 2002;92:1057–1059. Available at: <http://www.apha.org/codeofethics/ethics.htm>. Accessed November 2, 2004.
7. Soskolne C, Light A. Towards ethics guidelines for environmental epidemiologists. *Sci Total Environ*. 1996;184(1, 2):137–147. Available at: <http://www.iseepi.org/ethguide.htm>. Accessed November 2, 2004.
8. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, DC: Office of Protection from Research Risks (OPRR), NIH-PHS-HHS; 1988.
9. American Academy of Pediatrics Committee on Bioethics. Informed consent, parental permission, and assent in pediatric practice. *Pediatrics*. 1995;95:314–317.
10. Whittle A, Shah S, Wilfond B, Gensler G, Wendler D. Institutional Review Board practices regarding assent in pediatric research. *Pediatrics*. 2004;113:1747–1752.
11. Office of Human Research Protections. Special protections for children as research participants. Available at: <http://www.hhs.gov/ohrp/children/>. Accessed November 2, 2004.