AMBULATORY PEDIATRICS Volume 5, Number 1

Copyright © 2005 by Ambulatory Pediatric Association
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, 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.
- 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.
- 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.
AMPUTATION ANALYSIS

- 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)

Peter G. Szilagyi, MD, MPH, Chair
William Cooper, MD, MPH

Bernard P. Dreyer, MD
Ruth A. Etzel, MD, PhD
Christopher B. Forrest, MD, PhD
David P. McCormick, MD
Janet Serwint, MD
Lisa Simpson, MB, BCh, MPH
David Wood, MD, MPH

Consultants

Paul M. Darden, MD
Michael H. Farrell, MD
Joel Frader, MD, MA
Christine McHenry, MD
Herbert L. Needleman, MD
Virginia Ashby Sharpe, PhD

ACKNOWLEDGMENTS

This policy statement was developed under a cooperative agreement between the Ambulatory Pediatric Association and the Association of American Medical Colleges (AAMC) to undertake activities to enhance research integrity in general pediatrics. The cooperative agreement was funded by the Office of Research Integrity of the US Department of Health and Human Services.

REFERENCES