

---

 POSITION PAPER
 

---

# Code of Research Ethics

## *Position Paper of the Society for Adolescent Medicine*

### *Rationale*

#### **Why Does a Professional Society Need a Code of Research Ethics?**

Because the professions possess a body of abstract knowledge and a service orientation, they therefore occupy a distinctive niche in public life, securing certain privileges not accorded other occupations. One of the privileges granted by the public is self-governance, since the extended specialized professional education in both abstract knowledge and practical application precludes regulation of individual professionals by any one other than peers. In fact, it is how this regulation of practice is conducted in the public interest that represents the effective service orientation or ethicality of a profession (1).

The public has granted a certain level of autonomy to professional societies based on trust in the individual professional's responsibility and conscientiousness and on the profession's claim of self-regulation. Nonetheless, there continues to be a "tension between the acquisition of new knowledge and the fear of that knowledge [which] remains widespread in society" (2). The public certainly desires the benefits of new knowledge and usually wants these benefits without their attendant risks. At a minimum, though, the public demands assurances that knowledge is accurate, ethical conduct is assured, and subjects are carefully protected (3). As researchers work to learn new insights into treating illness and improving health, the public expects that they will conduct their work ethically and maintain as their highest priority the protection of research

subjects. This constitutes the basis of the social contract through which the public participates through volunteerism and supports research through government funding. Professional societies based on their responsibility and conscientiousness are empowered to encourage, enhance, and protect ethical standards that are attentive to the societal concerns regarding research.

Self-regulation can take a number of forms. Much self-regulation focuses on admission criteria such as educational preparation and proficiency, and is therefore administrative or proscriptive. Yet, Frankel noted that "[T]he scientific disciplines... are a prominent normative reference group, whose values and standards of appropriate research practices serve as guides by which individual scientists organize and perform their work and by which outsiders can understand and evaluate their performance" (4). In this light, he maintained that the societies should address common values and "by appealing to moral consciences and collective commitment to ensuring the integrity of science, . . . seek to evoke from scientists a higher standard of behavior than that which can be commanded through regulation" (4).

A code of ethics reflects a collective professional conscience committed to promoting ethical behaviors based on the collective experiences and distinct traditions of the scientific discipline. A code constitutes a basis for evaluating behavior and holding individual professionals accountable, and thereby creates a system in which individual professionals assume responsibility for the collective integrity of the society. A code of ethics also contributes to the socialization of new professionals, providing guidance on expected behaviors. Finally, a code of ethics establishes standards that may be used by legislative, administrative, and judicial bodies in adjudicating allegations of misconduct (4).

---

*Address reprint requests to: Society for Adolescent Medicine, 1916 NW Copper Oaks Drive, Blue Springs, MD 64015.  
Manuscript accepted January 26, 1999.*

### Why Does the Society for Adolescent Medicine Need a Code of Research Ethics?

The Society for Adolescent Medicine (SAM), a multidisciplinary organization, is devoted to the delivery of comprehensive acute, chronic, and preventive health care to youth and to the institution and execution of imaginative scientific research regarding all aspects of adolescence (5). SAM has committed itself to the establishment of a code of research ethics and its broad dissemination. It is hoped that by example, it will influence other organizations to do likewise.

The Society for Adolescent Medicine adopts a code of research ethics to identify the norms and values by which its members should act and with which it will initiate new members into the research life of its society. In so doing, SAM reaffirms its contract with the general population to seek knowledge through research in an irreproachably ethical manner.

A code of research ethics will be of particular value to SAM because research with adolescents presents many challenges. Adolescence itself is a period of profound cognitive, physical, social, and moral development, none of which adheres to a perfectly predictable course. During this time, adolescents experience a compelling need for privacy and develop a sense of identity apart from their parents. Parents, particularly those ill-prepared for these changes in their children, need reassurance from professionals that their parental role will be honored and their children protected. Establishing knowledge to promote healthy transitions from the dependency of childhood to a fully mature and capable adulthood is a noble endeavor, but one that requires clear vision, sensitivity, and integrity in the researchers attempting it. By providing the standards of responsible practice, a code of research ethics should foster trust and enlist both youth and their parents as collaborators in the effort.

While professional societies such as SAM can assume responsibility for defining, establishing, and disseminating ethical standards among their members, professional societies are generally remote from the institutions in which research is conducted and lack administrative mechanisms to enforce standards of conduct. In general, these institutions are often better able to enforce ethical standards. SAM will focus its efforts on the formation and continuing education of its members in the ethical conduct of research. Codes are absolutely necessary, although not sufficient, for the ethical well-being of all con-

cerned. The Society and its members must strive to promote the strong personal commitment of the individual researcher to the values, rights, and principles outlined in the code.

### *Code of Research Ethics for the Society for Adolescent Medicine*

This Code is based firmly on the Global Ethic (6) and the principles outlined in the *Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, known as the *Belmont Report* (7).

The Global Ethic, which seeks to identify those ethical elements common to the world's community of religions and traditions of honor, states:

Every human being without distinction of age, sex, race, skin color, physical or mental ability, language, religion, political view, or national or social origin possesses an inalienable and untouchable dignity, and everyone, the individual as well as the state, is therefore obliged to honor this dignity and protect it. There is a principle which is found and has persisted in many religious and ethical traditions of humankind for thousands of years: *What you do not wish done to yourself, do not do to others.* Or in positive terms: *What you wish done to yourself, do to others!*

Scientists and researchers must not give themselves over to morally questionable ideological or political programs or to economic interest groups nor should they justify research which violates fundamental ethical values. In the great ancient religious and ethical traditions of humankind is the directive: *You shall not lie!* Or in more positive terms: *Speak and act truthfully!*

Mutual respect and consideration must be cultivated so as to reach a reasonable balance of interests instead of thinking only of unlimited power and unavoidable competitive struggles. In the great ancient religious and ethical traditions of humankind is the directive: *You shall not steal!* Or in positive terms: *Deal honestly and fairly!*

The *Belmont Report* establishes three principles as the guiding spirit of ethical conduct: respect for personhood, beneficence, and justice. The application of these principles must be an integrated one, for on occasion situations may arise when dogged adherence to one principle invites violation of another. Consequently, easy answers and absolutism are to be avoided; acting ethically demands continual self-examination, discernment, and a willingness to approach ambiguity by consulting colleagues and others knowledgeable about the dilemma.

*Principle 1: Respect for personhood.* Honoring the dignity inherent in every human requires the acknowledgment of the right of self-determination. It rests on the principle of subsidiarity in which freedom of choice and action rests in the smallest unit of society with the capacity to exert it. In research activities, individual autonomy over personal decisions is to be respected and assiduously protected. There is also dignity to be respected in the families of subjects and the communities in which they live. Members of professional societies have additional responsibilities to their colleagues, especially those in training, for honoring their personhood, welfare, and development.

*Principle 2: Beneficence.* The principle of beneficence builds on the ancient dictum, *First, do no harm*, by requiring that research efforts must equally attend to doing good. Honoring the principle of beneficence demands that researchers commit themselves to advancing the common good, contributing to the welfare of humanity by establishing and disseminating new knowledge, and maximizing benefits while minimizing harm to subjects in their own research effort.

*Principle 3: Justice.* Justice demands that we give to all persons what is their due. Distributive justice requires that persons receive the benefits to which they are entitled. Investigators must scrutinize subject selection practices to ensure that all persons eligible for the research effort may have the opportunity to participate and potentially gain from research offering potential benefit. Subjects should be selected equitably with appropriate racial and sexual representation. Contributive justice requires that the burdens of research participation not be imposed in a way that affects some people unfairly. In addition, the requirement to act justly extends to one's colleagues and collaborators in honoring their work and contribution.

### *The Code of Ethics in Research Development*

#### **Creation of the Research Question and Design**

- Society for Adolescent Medicine member scientific investigators should maintain basic competence in research methods and seek competent methodologic and analytic support when it is indicated. The principle of beneficence demands that the contribution of research subjects be honored and optimized so that the objective of improving health and welfare is achieved.

- Research efforts involving human subjects should be scientifically sound and feasible, while all attendant risk to subjects should be made proportional to their particular circumstances.
- Research projects with little statistical probability of achieving study objectives should be avoided. Investigators are duty bound to ensure that the research experiences contributed by study subjects in good faith be evaluated and reported as understood by the subjects in the consent process.
- Society for Adolescent Medicine members should consider the effect of study results on identifiable communities in which studies are conducted. Communities should be understood to be sponsors and consumers of research. SAM members should make efforts to elicit and respond to community concerns during the development of research projects.
- Investigators conducting sponsored research must maintain independence. This extends to study design, conduct, interpretation, and reporting of study results. Investigators must always be aware of their moral obligation to hold the public interest above the interest of sponsors if a conflict arises.
- Investigators should undertake animal experimentation only to advance knowledge, when known alternatives are scientifically inadequate, and when scientifically valid conclusions will be possible. Study design must ensure respect and due concern for animal health and welfare.

#### **Formal Review Process**

- Society for Adolescent Medicine members should strive for honest appraisal of their own limitations, seeking peer review of research initiatives, making efforts to learn from critical evaluation, and assuming good faith on the part of colleagues. No member should discriminate against or harass colleagues who have offered criticism, nor should a member retaliate against a colleague who raises concerns about a member's misconduct.
- Investigators must obtain objective ethical review of proposed projects before contact with human subjects. These reviews are generally conducted by institutional review boards (IRBs). Researchers should adhere to requirements imposed by IRBs.
- Investigators must be alert to conflicts of interest, prudently engage in relationships that might precipitate such conflicts, and disclose such conflicts to the affected parties. Investigators are required to disclose all relevant financial, personal, or professional relationships that might lead to a conflict

of interest, for themselves and their family members, to their institutions, in their writings and public speeches, and to the sponsors of their research funding.

### Consent Process

- Society for Adolescent Medicine members must honor the role of parents or guardians in the lives of adolescents and carefully balance the developing maturity of the adolescent with the benefits of adult engagement in the research process (8). Adult involvement becomes increasingly important if adverse consequences are possible from research with higher levels of inherent risk.
- Society for Adolescent Medicine members, in their work with adolescent research subjects, should respect the adolescent's evolving intellect, judgment, and experience. The adolescent's capacity for independent decision making should be respected in a careful balance of the individual adolescent's experience and personal circumstances with the inherent research risks. The adolescent's right to autonomy must be honored in the research process with clear, patient, and complete explanations of the research and implications which can be readily understood by the adolescent (8).

### Management of Study Data

- The investigative team is obligated to honor the consent agreement related to the confidentiality of subject information. Consent agreements should explicitly note the circumstances in which there are limits on confidentiality in the professional-client relationship (e.g., child abuse reporting requirements). SAM investigators should ensure that there is a written confidentiality policy understood and adhered to by the full team which addresses both verbally shared and recorded information collected on subjects. The principal investigator is responsible for the integrity of the system.
- In general, information maintained in study databases should not include personal identifiers. In special circumstances, viz. database linkage requiring personal identifiers, investigators assume greater responsibility for providing additional protections for the confidentiality of the information. Under no circumstance may databases which

include direct or potential personal identifiers be made available to investigators external to the original IRB-reviewed investigator team and project unless specific subject consent for that practice has been expressly obtained.

- Research records should be maintained for a minimum period of 5 years after publication for reference purposes should questions arise. The integrity of the scientific process rests on the capacity to challenge and question and the existence of the primary data source makes the process possible. Investigators must keep in mind that the end of the process is not publication, but the advancement of knowledge.

### Authorship

- Primary or submitting authors assume responsibility for the contents of the manuscript and the accuracy of all primary data, for determining all legitimate coauthors, and specifying the order in which the authors' names appear (4).
- Legitimate coauthors are those who make significant scientific contributions to the work and who share responsibility for the results. An author is first of all a writer, and the criterion of merit is the advancement of knowledge (6). Authors must substantially contribute to each of three activities: (a) conception and design, or analysis and interpretation; (b) drafting the article or revising it critically for important intellectual content; and (c) approval of the final version to be published (10).
- Granting honorary authorship is an unacceptable practice. Individuals with contributions not meriting coauthorship should be acknowledged; such contributions include clerical assistance, arranging for research subjects, and computer programming.
- The scientific contributions of students must be acknowledged.
- Scholars are obligated to acknowledge the use of the intellectual property of others.
- Teachers and mentors are not to appropriate the work of students or trainees as their own.

### Responsibility to Disseminate Study Results

- Researchers must truthfully report study data. Lying, misrepresenting, falsifying, and selectively reporting only favorable data are all reprehensible practices.
- After the original investigator has completed anal-

ysis and all prior rights to publication are satisfied, and unless specifically prohibited by provisions of the subject consent process or the proprietary nature of the data, investigators should open access to research databases to competent and qualified researchers. The original IRB-reviewed investigator must ensure that no personally identifying data exist in shared databases, including the capacity to link database information with other sources to identify subjects. It is expected that the requesting investigator will bear the expense of the project. This practice of data sharing furthers the advancement of knowledge by expanding the scope of the original study question through ancillary analyses and optimizes the societal benefit to be derived from the contributions of study subjects.

- If datasets are particularly complicated or the conditions under which the data were collected may affect the interpretation of results, it is appropriate for the original investigator to suggest a collaborative relationship to fully share all aspects of the research design, data collection procedures, and unique features of the database for the purpose of ensuring accuracy. This collaborative relationship does not imply automatic authorship on resulting publications; the criteria for authorship must be met.
- Society for Adolescent Medicine members should decline participation in peer review if it poses a conflict of interest for them. Conflicts of interest should not be narrowly defined by institutional or financial relationship, but should extend to any situation in which a reviewer knows she or he cannot deliver a fair and objective review. No reviewer should use the review process to further his or her own research by unnecessarily delaying the publication timetable or appropriating the work of others entrusted for review.
- Society for Adolescent Medicine members should consider the effect of study results on the communities in which studies are conducted. SAM members should make efforts to ensure that study results are provided to guide and support relevant community programmatic initiatives. SAM members should be committed to the improvement of the communities in which adolescents live. Communities which have provided support, volunteer time, or accepted intrusion into their privacy should be provided with a thorough review of research findings.

### Particular Responsibilities

- All SAM members, whether or not they are involved in a formal institutional training program, should consider mentorship and the training of junior investigators a professional responsibility. All members are obligated to act as exemplary role models adhering to the highest standards of conduct.
- Society for Adolescent Medicine members who function within training and educational programs should ensure that values and ethical principles governing research are understood by trainees and students. This process should be formal and systematic, not haphazard or assumed.
- Effective and beneficent mentoring is premised on respect for the junior partner. It elicits initiative and independent thinking while providing guidance and supervision. Mentors must assiduously avoid acting in their self-interest at the expense of their junior partners.
- Society for Adolescent Medicine members must hold each other accountable in the conduct of research. Preserving the integrity of the research process and thereby maintaining and enhancing the goodwill of our larger society demands vigilance and engagement from us all. SAM members must be willing to advise and confront and, failing resolution, report concerns to appropriate authorities for private investigation. SAM members should approach this duty respectfully and confidentially and never exploit the situation for character assassination or personal gain.

This document relies heavily on the work (Reference 4) of Mark S. Frankel, Director of the Scientific Freedom, Responsibility, and Law Program at the American Association for the Advancement of Science in Washington, DC, who summarized key tenets of codes adopted by other professional societies.

### References

1. Freidson E. The Test of autonomy: Professional self-regulation. In: *The profession of medicine: A study of the sociology of applied knowledge*. New York: Harper and Row, 1970:137-40.
2. Olson S, for the Board on Biology, National Research Council. Science and scientists from the public's perspective. In: *Shaping the future: Biology and human values*. Washington, DC: National Academy Press, 1989:28-32.
3. Kass NE, Sugarman J, Faden R, Schoch-Spana M. Trust: The fragile foundation of contemporary biomedical research. *Hastings Center Report* 1996;26:25-9.
4. Frankel MS. Professional societies and responsible research conduct. In: *Responsible science: Ensuring the integrity of the research process*. Vol. II. Washington, DC: National Academy

- of Sciences, National Academy of Engineering, and Institute of Medicine, 1992-1993:26-49.
5. Society for Adolescent Medicine. Aims and scope. Masthead of the *Journal of Adolescent Health*, the Official Publication of the Society.
  6. Declaration toward a global ethic: Parliament of the world's religions. Chicago, IL: Global Ethic Foundation, Tubingen, Germany, September 4, 1993.
  7. 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. Office of Protection from Research Risks (OPRR). NIH-PHS-HHS. Washington DC: U.S. Government Printing Office, 1988.
  8. Society for Adolescent Medicine. Guidelines for adolescent health research. *J Adolesc Health* 1995;17:264-9.
  9. Susser M. Editorial: Authors and authorship—reform or abolition? *Am J Public Health* 1997;87:1091-2.
  10. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. *JAMA* 1997;227:927-34.
  11. Integrity and misconduct in research: Report of the Commission on Research Integrity to the Secretary of Health and Human Services, the House Committee on Commerce, and the Senate Committee on Labor and Human Resources, 1995. United States Department of Health and Human Services.
  12. Association of American Medical Colleges. Developing a code of ethics in research: A guide for scientific societies. Washington, DC: 1998.

*Prepared by:*

Audrey Smith Rogers, Ph.D., M.P.H. (Chair)  
National Institute of Child Health and Human  
Development  
Bethesda, Maryland

Sara B. Kinsman, M.D.  
Children's Hospital of Philadelphia  
Philadelphia, Pennsylvania

John S. Santelli, M.D., M.P.H.  
Centers for Disease Control and Prevention  
Atlanta, Georgia

Tomas Jose Silber, M.D., F.S.A.M.  
Children's National Medical Center  
Washington, DC