

*University of Tennessee*  
Symposium on Scientific Integrity and  
Preventing Research Misconduct

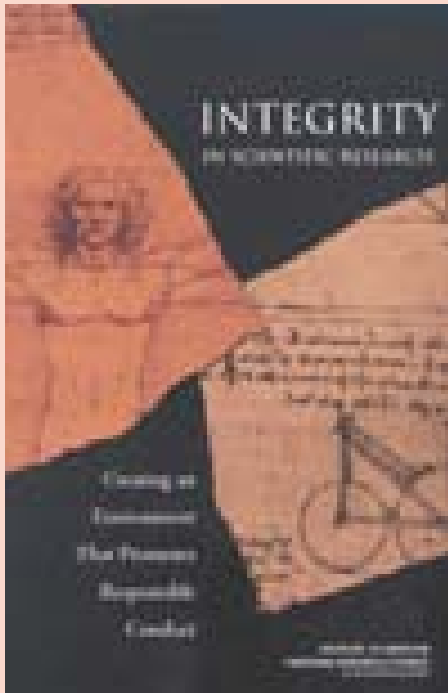
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# Scientific Integrity

*“Considerable effort has been devoted to the task of defining research misconduct and elaborating methods and for investigating allegations of misconduct. Much less attention has been devoted, however, to the task of fostering a research environment that promotes integrity.”*



## Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct

Committee on Assessing Integrity in Research Environments  
National Research Council, Institute of Medicine,  
National Academies Press, 2002

<http://www.nap.edu/catalog/10430.html>

# Public Trust

- The pursuit and diffusion of knowledge enjoy a place of distinction in American culture, and the public expects to reap considerable benefit from the creative and innovative contributions of scientists.
- Most Americans have a positive attitude toward science and technology and are willing to demonstrate their support through public investments in science and research institutions.
- Public funding is based on the principle that the public good is advanced by science conducted in the interest of humanity.
- Such support is qualified, however. The public will support science only if it can trust the scientists and the institutions that conduct research.

# Integrity in Research

- Integrity in research is essential for maintaining scientific excellence and for keeping the public's trust. Integrity characterizes both individual researchers and the institutions in which they work.
- For a scientist, integrity embodies above all the individual's commitment to intellectual honesty and personal responsibility. It is an aspect of moral character and experience.

# Integrity in Research

- For an institution, it is a commitment to creating an environment that promotes responsible conduct by
  - embracing standards of excellence, trustworthiness, and lawfulness and then
  - assessing whether researchers and administrators perceive that an environment with high levels of integrity has been created.

# Integrity in Research

- Many practices are likely to promote responsible conduct. Individuals and institutions should use these practices with the goal of fostering a culture in which
  - high ethical standards are the norm,
  - ongoing professional development is encouraged,
  - and public confidence in the scientific enterprise is preserved.

# Conclusions

Attention to issues of integrity in scientific research is very important to the public, scientists, the institutions in which they work, and the scientific enterprise itself.

- No established measures for assessing integrity in the research environment exist.
- Promulgation of and adherence to policies and procedures are necessary, but they are not sufficient means to ensure the responsible conduct of research.
- There is a lack of evidence to definitively support any one way to approach the problem of promoting and evaluating research integrity.

# Conclusions

- Education in the responsible conduct of research is critical, but if not done appropriately and in a creative way, then education is likely to be of only modest help and may be ineffective.
- Institutional self-assessment is one promising approach to assessing and continually improving integrity in research.
- Existing data are insufficient to enable it to draw definitive conclusions as to which elements of the research environment promote integrity.
- Empirical studies evaluating the ethical climate before and after implementation of specific policies or practices are lacking.

# The Research Environment

- The research environment changes continually, and these changes influence the culture and conduct of research.
- As with any system being scientifically examined, the research environment itself contains variables and constants.
- The most unpredictable and influential variable is the individual scientist.

# The Research Environment

- The human contribution to the research environment is greatly shaped by each individual's professional integrity, which in turn is influenced by that individual's educational background and cultural and ethical upbringing and the resulting values and attitudes that contribute to identity formation, unique personality traits, and ethical decision-making abilities.

# Individual Level

For the individual scientist, integrity embodies above all a commitment to intellectual honesty and personal responsibility for one's actions and to a range of practices that characterize the responsible conduct of research, including:

- intellectual honesty in proposing, performing, and reporting research;
- accuracy in representing contributions to research proposals and reports;
- fairness in peer review;
- collegiality in scientific interactions, including communications and sharing of resources;

# Individual Level

- anticipate, reveal, and manage individual and institutional conflicts of interest;
- transparency in conflicts of interest or potential conflicts of interest;
- protection of human subjects in the conduct of research;
- humane care of animals in the conduct of research; and
- adherence to the mutual responsibilities between investigators and their research teams.

# Institutional Level

Institutions seeking to create an environment that promotes responsible conduct by individual scientists and that fosters integrity must establish and continuously monitor structures, processes, policies, and procedures that

- provide leadership in support of responsible conduct of research;
- encourage respect for everyone involved in the research enterprise;
- promote productive interactions between trainees and mentors;
- advocate adherence to the rules regarding all aspects of the conduct of research, especially research involving human participants and animals;

# Institutional Level

- Arrange timely and thorough inquiries and investigations of allegations of scientific misconduct and apply appropriate administrative sanctions;
- Offer educational opportunities pertaining to integrity in the conduct of research;
- Monitor and evaluate the institutional environment supporting integrity in the conduct of research and use this knowledge for continuous quality improvement.
- Provide support mechanisms, such as ombudspersons, that research team members can turn to with concerns about integrity, including reporting suspected misconduct.

# Mentoring

- The example set by a respected mentor is perhaps the most effective way to ensure that trainees develop skills in moral reasoning and personal integrity that will be sustained throughout ones scientific career.
- The relationship between a mentor and trainee should be characterized by mutual respect, caring and friendship, focused on sharing the mentor's experience and wisdom derived there from for the benefit of the trainee's professional development as a scientist.

# Professionalism

- Requires mastery of a defined body of knowledge, not just skill
- Is conducted primarily for the benefit of another rather than oneself
- Economic reward is not the primary motivation
- One's conduct is governed by one's professional peers, according to standards established by and enforced by one's peers
- Personal integrity and commitment to excellence is an enduring characteristic

# Accountability and Validation

- Professionals willingly agree to be held accountable for their actions
- Professions rely upon external assessment and validation of ones knowledge and skills
- Credentialing, in the form of accreditation and certification are proven effective tools
- Clinical research has been slow to adopt professionalism as a model for conduct



# Vulnerability and Informed Consent

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Toward a more efficient and effective  
process...

# Informed Consent

- Poorly conceived, poorly executed
- Excessive focus on the consent form
- Conflated, confused and conflicted
- Need for fundamental reform

# Basic elements of informed consent:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

# Basic elements of informed consent:

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

# Additional elements of informed consent, as appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

# Vulnerability

- What makes one vulnerable?
- How should we deal with vulnerable subjects?

Thank you for participating today!