The Role of Universities in Promoting Research Integrity

David B. Resnik, JD, PhD, Bioethicist, NIEHS/NIH

This research was supported by the intramural program of the NIEHS/NIH. It does not represent the views of the NIEHS, NIH, or US government.
Introduction

Universities play a crucial role in promoting research integrity both on campus and off.

- Education
- Policy development
- Compliance/oversight
- Consultation
- Collaborations with other institutions
- Assessment
- Research on research integrity
- Leadership
Since 1989, the NIH has mandated instruction in responsible conduct of research (RCR) for students supported by PHS grants. The mandates have expanded over the years and now include individuals on training grants, career development awards, research education grants, or dissertation research grants.

Education must consist of in-person sessions, though online supplemental sessions are allowable. Education must include 8 hours addressing core topic areas:

- Data management, misconduct, authorship, collaboration, publication, peer review, mentoring, conflict of interest, human subjects, animal subjects, and social responsibility.
Education

- In 2009 the NSF began requiring that all undergraduate students, graduate students, and postdocs supported by NSF funds receive instruction in RCR, as required by the America Competes Act (2007).
- Institutions must have a plan to provide RCR training.
- NSF does not mandate format or content of the training.
Education

- These mandates are helpful and important, but are they enough?
- Should institutions go beyond the federal mandates and extend RCR education to individuals not specifically covered, including, possibly, faculty?
- Broadening the educational program can help send a message the institution values research integrity.
- It can also be easier to track compliance if entire groups are required.
Education

- In 2011, Greg Dinse and I sent a brief survey to the top 200 US research institutions, ranked by research funding.
- 72% response rate.
- 52.1% went beyond the federal mandates and required others to receive training, including:
  - all students in selected programs (23.6%)
  - all students participating in externally funded research (12.5%)
  - all graduate students (11.1%)
  - all faculty/staff participating in externally funded research (9.7%)
  - all postdoctoral students (8.3%)
  - all doctoral students (4.9%)
  - all faculty/staff involved in human subjects research (4.9%)
  - and all faculty/staff involved in animal research (2.1%)
Education

- We looked at the impact of funding level, public vs. private, geography, and presence of a medical school.
- Only presence of a medical school significantly impacted whether the institution went beyond federal mandates (62.3% vs. 37.3%, P = .004).
- Institutions with medical schools were more likely to require all postdocs, students in selected programs, and faculty/staff participating in human subjects research to take RCR training.
Education

- Variety of modalities
- Online modules (CITI often used)
- Lectures
- Conferences/workshops
- Seminars
- For credit courses
- Mentoring
Education

- Skepticism about moral education
- This topic is related to a very old problem in philosophy
- Can virtue be taught? (Plato/Meno).
Some reasons for skepticism:

- People are naturally good or bad; education is useless.
  - Reply: Nature does strongly influence our behavior but the environment still plays a key role.

- It’s too late; a person’s character is formed by the time they enter college or university.
  - Reply: It’s not too late. Research shows that moral learning and development continues into professional life.

- Bad people won’t listen; you’ll only reach good people, who don’t need education anyway.
  - Reply: Maybe some won’t listen, but others will. It is not as simple as good vs. bad. Some people not understand the ethical standards or are under pressure/stress, and they may act unethically without education, training, proper motivation and reassurance.
Education


- This study showed no positive effect of RCR education or training on misbehavior. In fact, people who had training were more likely to have misbehaved.

- However, this was a survey that was not properly designed to test the relationship between RCR education and behavior. For example, the type of education people received or when they received it was not controlled.
Education


• Both of these studies showed that education can improve knowledge and awareness, but not necessarily reasoning, attitudes or behavior.
Education


• Meta-analysis of different empirical studies. Shows that education can influence knowledge, awareness, and reasoning and that stand alone courses are more effective than ethics education embedded into other courses.
Education

- This was an experimental study in which two RCR education groups (stand alone and embedded) were compared to a control (no RCR education).
- There was pre- and post-testing for various measures related to ethical.
- Evidence that education enhances RCR knowledge, awareness, reasoning, and attitudes.
- No evidence that stand alone courses are more effective than embedded.
Policy development

- Policy development is essential so that students, faculty and staff understand the expectations for behavior.
- NIH/NSF require institutions to develop policies on misconduct, conflict of interest, human subjects, animal subjects, laboratory safety.
- Many also have policies pertaining to other areas, such as data access, retention, and ownership; authorship, publication, and intellectual property, and technology transfer.
- Policies should be well-publicized and covered during educational sessions.
- Faculty should have input into policy development so they will have buy-in.
Compliance and oversight

- Institutions need procedures and mechanisms for ensuring compliance and overseeing research activities.
  - Institutional review board
  - Animal care and use committee
  - Conflict of interest committee
  - Laboratory safety committee
  - Biosafety committee
  - Radiation safety committee
  - Research ethics committee

- Institutional officials: Research Integrity, Ethics or Compliance Officer
Compliance and oversight

- Auditing research
  - Human subjects
  - Animal subjects
  - Research conducted under Good laboratory practices (GLP)
  - All research?
- Receiving reports of illegal or unethical activities (e.g. misconduct, violations of human or animal research rules, etc.)
- Student, faculty, staff should know whom to report to.
- Reporting should be safe, encouraged.
- Whistleblowers should be protected.
- Confidentiality and due process should be maintained.
- Standard operating procedures should be carefully followed.
Consultation

- It is important to provide ethics consultation services for researchers who have an ethical question, problem, issues, or concern that is not necessarily reporting a violations of rules.
- Many ethical issues arise in research.
- Human and animal subjects.
- Research integrity, especially authorship, publication, and data sharing issues.
- Consultation should be confidential, neutral, readily available by email, phone, or in person.
Consultation

- Consultants can provide information about relevant policies and institutional resources.
- Consultants should be good at listening and mediating.
- Consultants may give advice but not tell people what they have to do.
- Consultants should have appropriate education and experience related to ethics and science.
- In some cases, consultants will have an obligation to report suspected violations of rules that they learn about. In these situations, complete confidentiality may not be guaranteed.
Collaboration

- University–based researchers enter into many different types of collaborative arrangements.
- National, international
- Public, private
- Small, large (e.g. multicenter clinical trials)
- It is important for collaborators to have a common understanding of the ethical and legal standards that apply and to follow those standards.
- Universities can aid this process by establishing guidelines for collaborative research and supporting administrative offices that deal with collaborations.
International collaborations can be especially challenging, due to differences in culture, language, economics, politics, the law, etc.

There are also tensions in partnerships with private companies, which may not embrace academic values, such as openness, publication, objectivity, and sharing of data and materials.

Legal documents, such as material transfer agreements, data use agreements, and collaboration agreements can help establish expectations for relationships.
Universities should periodically assess their efforts to promote RCR.
Assessment should include studies of education, behavior and attitudes, compliance, resources, policies.
Research

- Research on research integrity includes conceptual research (normative, policy) and empirical research.
- The Office of Research Integrity has sponsored research on research integrity since the late 1990s.
- The field is diverse and growing.
- Research can help support policy development, education, compliance and oversight.
Leadership

- Ethical leadership is essential for promoting integrity in research.
- Institutional leaders should demonstrate their commitment to ethics by their example, allocation of resources (money, staffing), and presence at ethics events (workshops, conferences, etc.).
- People are sensitive to hypocrisy and are less likely to behave ethically if they sense that ethics leaders are not committed to ethics.
- Unethical leadership can lead to corruption throughout the institute and have a demoralizing affect on researchers.