The Need for Global Strategies for Training Students in RCR

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Three kinds of instruction are typically presented to trainees in RCR / research integrity education:

- "How to" issues and procedural aspects of good research
- Institutional policies, governmental regulations, professional norms, and standards of practice
- Recognition and analysis of ethical values and questions in research; collegial engagement

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Professional socialization

Prevention of misconduct????

Evaluating RCR instruction

- Prevention of misconduct is ***not*** clearly assessable; academic knowledge and professional skills are assessable.
  - Does student understand relevant ethical concepts and standards in context?
  - Can the student use coherent moral arguments?
  - Can the student recognize ethical values and problems, examine them rationally, and plan a course of action?
- Each depends upon students' knowledge/understanding of the "how-to's" and professional norms of research.
- The last two also depend upon students' moral reasoning skills and ability to articulate ethical values.

Successful collaborative research requires investigators' clear communication and mutual understanding of the values and practice standards that shape their work.

International collaboration challenges researchers to negotiate variations in values and practice standards may affect their ability to work together.

Most formal statements of research ethics and research integrity have been created:

- Retrospectively
- In response to particular questions or problems
  - Apparent violations of unwritten rules
  - New technologies that raise new issues
  - In specific cultural and historical contexts
- Under public pressure and scrutiny
- With limited consensus among scientists and regulators

These characteristics limit the applicability of specific countries' policies internationally.

U.S. research funding agencies seek to promote high ethical, health, and safety standards in research through specific policies.

NIH requires *all* funded investigators and institutions, *irrespective of location*, to adhere to its policy requirements governing ethics and research integrity.

NIH funding is contingent on institutional compliance with certain policies, spelled out by institutional contract with collaborators.

- Debarment and Suspension
- Drug & Smoke-Free Workplace
- Lobbying
- Financial Conflict of Interest
- Research Misconduct
- Data Management / Sharing
- Research on Fetal Tissue
- Human Embryonic Stem Cell Research
- Inclusion of Women, Children, and Minority Participants

- Human Subjects/ Education on Protection of Human Subjects (IRB)
- R-DNA / Human Gene Transfer Research (IBC)
- Vertebrate Animals (IACUC)
- RCR Instruction
- DOC Export Restrictions

ORI's Core Instructional Areas in RCR (2000)

- Data management
- Mentor/trainee responsibilities
- Publication and authorship
- Peer review
- Research with human beings
- Research involving animals
- Research misconduct
- Conflict of interest and commitment
- Collaboration

How should RCR educators prepare their trainees for international collaboration?

- Regulatory structures and professional standards in research are evolving everywhere, with uneven coverage.

- Each core area of RCR involves ambiguity and potential conflict among national and international policies.

Significant U.S. Consensus on Standards

- Human research
- Animal research
- Misconduct / responsible conduct
- Authorship and publication

Growing U.S. Consensus on Standards

- Data management
- Conflict of interest
- Mentoring

Limited U.S. Consensus on Standards

- Peer Review
- Collaboration

(Heitman & Bulger 2005)

Points of International Ambiguity and Potential Conflict

Human research

- Multiple oversight structures, multiple levels of complexity
- Definition of vulnerable populations
- Inclusion of women, children, “minority populations”

Animal research

- Clear standards in North America and Europe but variable elsewhere

Misconduct / responsible conduct

- Basic standards in US and Europe but highly variable elsewhere
- Cultural interpretation may lie behind perception of misconduct

Authorship and publication

- ICMJE criteria or other
- Differing professional roles and hierarchies
- Dual-use research and access to methods and data (export controls)

Points of International Ambiguity and Potential Conflict

Data management

- Language used for record keeping
- Dual-use research and access to methods and data
- Privacy, confidentiality, and HIPAA

Conflict of interest

- Meaning of gift giving
- Variable levels of monetary value and meaning
- Variable access to drugs and equipment

Mentoring

- Variable social roles and hierarchies
- Limited choice of mentors in small systems
- Mentors as culture brokers in an international context

Points of International Ambiguity and Potential Conflict

Peer review

- International peers' different backgrounds
- Peers' familiarity with local contexts
- Fluency in both languages

Collaboration

- Who benefits from collaboration
- Whose standards when and why
- Communicating over physical and cultural distances

Research education and training must respond to demographics.

- International trainees are essential to continued growth of the research enterprise in industrialized countries (Butz 2003).
- In 2004-5, 30% of graduate students and 50% of postdoctoral fellows in U.S. science programs were from other countries (NRC 2005; NSF 2006); over 50% expect to stay in the US in research careers (Mervis 2003; Butz 2003).
- Research institutions in the US, UK, Germany, France, Australia, and Japan compete for the best trainees (ACE 2006). Since 1999, the Bologna Process has significantly increased the numbers of international trainees in Europe and the competitiveness of European higher education in science (Europa 2007).

RCR education for a global future requires strategies to recognize and address differing values and practices in research worldwide.

- International trainees need focused instruction to help them succeed in their new environments (Heitman et al. 2007).
- Tomorrow's investigators must be able to work internationally.
- To promote research integrity in a global environment, RCR instructors must learn about standards and practices in multiple countries and help their trainees and colleagues understand, interpret, and integrate them.

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Special section on research integrity education

www.academicmedicine.org

Guest editors: Elizabeth Heitman & Lida Anestidou

- History and policy
- Administrative view
- Trainees' knowledge of RCR
- Effects of training & mentoring
- Goals of RCR training
- On-line RCR training
- RCR Education Committee
- Scientific societies & RCR
- RCR across the university

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