

# Formal Education in Research Ethics and Responsible Conduct of Research (RCR)

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Between 1989 and 2007, 5 mandates for US institutions to provide education in research ethics and RCR for (all) trainees.

1989 – PHS/NIH requires “formal or informal” education in RCR to trainees in NRSA research training programs.

1994 – NIH encourages RCR education for all trainees

2000 – OHRP mandates education on human research protection

2000 – ORI mandates RCR education for all funded on grants\*

2007 – America COMPETES Act mandates RCR education for all trainees on NSF research or training grants

## Basic instruction in research ethics and responsible conduct of research includes:

- “How to” issues and procedural aspects of good research
- Institutional policies, governmental regulations, professional norms, and standards of practice
- Recognition, analysis, application, and reinforcement of ethical values and questions in research
- Professional socialization, including collegial engagement in discussion of ethical standards, controversies, and emerging questions

## Key Instructional Areas in RCR

- Data management
- Mentor & trainee responsibilities
- Publication & authorship
- Peer review
- Collaborative science
- Research with humans
- Research with animals
- Research misconduct
- Conflict of interest & commitment
- Ethical principles
- Moral reasoning
- Codes of ethics
- Professionalism
- Laboratory safety
- Environmental concerns
- Epidemiology
- Biosafety & biosecurity
- Scientists' roles in society
- Scientific method & objectivity
- Creativity & innovation

## What Are Universities Doing Now ?

- Limited data available - Programs not centralized
  - 2008 survey of Association of American Universities
  - 2009 survey of CTSA programs
  - CITI's records
- Online modules (with tracking for compliance)
- Orientations for new trainees
- Targeted workshops – special topics or audiences
- Semester courses – required or elective
- Requirements for faculty?
- Patchwork quilts and tapestries

## Lecture

- Many students, many programs; few/many instructors - team
- Goals: common basic knowledge for all; centralization; standardization
- Content: Facts (history, policies, regulations, standards of practice, professional norms); case examples
- Format: One time orientation; workshop; short course, semester course
- Instructors: Content experts, ethicists
- Audience: Trainees, usually beginners
- Communicates authority and institutional commitment, but lack of concern for engagement, judgment

## Seminars and discussion groups

- Smaller groups; discipline or problem-based approach
- Goals: Discuss personal views; reinforce common values; teach and practice problem solving
- Content: Recognition, analysis, application, and reinforcement of ethical values and norms
- Format: Ongoing regular (monthly, quarterly) sessions; reading with a case example
- Instructors: Experienced investigators and “facilitators”
- Audience: Trainees, usually beginners
- Promotes interaction and professional socialization; may not convey facts

## Online courses and modules

- Many students, many programs; few or no instructors
- Goals: common basic knowledge for all; centralization; standardization; documentation/ tracking
- Content: Facts (history, institutional policies, regulations); some cases
- Format: One time; self-study; self-testing
- Instructors: Outside content experts
- Audience: Trainees, usually beginners
- Suggests interaction and discussion not important; stresses knowledge and documentation of compliance

## Case conference or ‘journal club’

- Discipline or problem specific, small to large group
- Goals: Application of standards, skills to “real” question(s)
- Content: Facts (history, institutional policies, regulations); practical application some cases
- Format: Ongoing regular (monthly) sessions; complex case or article with background reading
- Instructors: Senior and junior investigators; “facilitators”
- Audience: Trainees at all levels, some faculty and staff
- Suggests collegial discussion important; new emerging questions worthy of attention; continuing education useful

## Available Materials

- Textbooks: Many in biomedical research;  
Professional reports
- Journals: Specialty ethics journals  
General research journals
- Videos: Professional and popular
- Websites: ORI resources; CITI and other online courses
- News stories from popular media
- Published cases and real cases (anonymized)

## An Integrated Graduate Program

- Online course as self-study introduction
- Required “Foundations of Ethics/RCR” course for trainees
  - Lectures on key concepts, history, policies
  - Textbook(s), reports, journal articles, assigned for depth
  - Exams test students’ knowledge
  - Case discussion applies knowledge to hypothetical practice
- Regular departmental case conference for all:
  - Examine articles and news stories in the professional literature
  - Examine news stories from the popular media
  - Examine issues in the institution or department
- Question on research ethics/RCR on qualifying exam
- Senior faculty take part as role models of life-long learning