NIH Responsible Conduct of Research (RCR) Requirements

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Objective

• To Discuss the Impact of Responsible Conduct of Research Instruction Requirements on Submission of NIH Applications
• To Describe the NIH Requirements for Submitting Continuation (Type 5) Applications

National Science Foundation (NSF)

• National Science Foundation (NSF)
  Implementation of Section 7009 of the America COMPETES Act
  Final Rule August 20, 2009
• National Science Foundation (NSF)
  Responsible Conduct of Research Training Requirement – University of Kentucky
  Compliance Process (Interim Policy) – Office of Sponsored Projects Administration
  http://www.research.uky.edu/NSF_RCR_process.pdf
Policy History
National Institutes of Health/RCR

- 1989: Institutional Training Grants – Applications Must Describe RCR Instruction
- 1994: Update of Policy
- Periodically with Guidelines: Research Education; Career; Fellowship
- 2009: Update – Significant Changes

National Institutes of Health (NIH) Update on the Requirements for Instruction in the Responsible Conduct of Research

- Notice Number: NOT-OD-10-019
- Release Date: November 24, 2009

NIH RCR Instruction Notice Includes:
- Instructional Components
- Special Considerations by Type of Award
- Application Procedures (New and Continuation)
- Peer Review
- Reporting Requirements (Progress Reports)
- Compliance/Documentation
- Resources
Applicability
NIH RCR Requirements
- ALL NIH Supported Trainees, Fellows, Participants, & Scholars
- Any NIH Training, Career Development (Individualized or Institutional), Research Education Grant, or Dissertation Research Grant
- NEW and Renewal Application 01/25/10
- All Continuation (Type 5) Applications 01/01/11

Applicability/Examples
- Dissertation: D43, D71
- Fellowship: F05, F30, F31, F32, F33, F34, F37, F38
- Career Development: K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2
- Research Education: R25, R36
- Training: T15, T32, T34, T35, T36, T37, T90/R90, TL1, TU2
- U2R

NIH RCR
Basic Principles
1. Essential Component of Grant/Impacts Funding Decisions
2. RCR Ongoing/Appropriate to Career Stage
3. Individual Award Recipients Assume Individual Responsibility for Their Instructions
4. Research Faculty Participate as Role Models
5. Face to Face Discussions Should be Included/On-Line May be Component But Not Sufficient
6. RCR Instruction Carefully Evaluated in Applications
What RCR Information Do You Include in New Applications?

NIH Policy RCR Five* Instructional Components

1. Format
2. Subject Matter
3. Faculty Participation
4. Duration
5. Frequency of Instruction

*Plus Monitoring Documentation

Component 1 - Format*

- Substantial Face-to-Face
- Combination Didactic & Small Group
- Research Training Faculty Participation
- May Incorporate On-Line But Cannot be Sole Means of Instruction

*NIH Recommendation
# Component 2 - Subject Matter

1. Conflict of Interest – Personal, Professional, and Financial
3. Mentor/Mentee Responsibilities and Relationships
4. Collaborative Research Including Collaborations with Industry
5. Peer Review

# Component 2 - Subject Matter Continued

6. Data Acquisition and Laboratory Tools; Management, Sharing and Ownership
7. Research Misconduct and Policies for Handling Misconduct
8. Responsible Authorship and Publication
9. The Scientist as a Responsible Member of Society, Contemporary Ethical Issues in Biomedical Research, and the Environmental and Societal Impacts of Scientific Research

# Subject Matter Continued

Examples of Courses Not Sufficient to Cover All Topics:

* Professional Ethics
* Ethical Issues in Clinical Research
* Research Involving Vertebrate Animals
Component 3 - Research Faculty Participation

- Informal & Formal Training
- Formal: Discussion Leaders; Speeches; Lecturers; Course Directors
- Rotation of Training Faculty

Component 4 - Duration

- Substantive Contact Hours
- Recommend at Least 8 Hours
- Encourage Semester Long Courses

Component 5 - Frequency

- Optimize RCR Instruction for Career Stage (Undergraduate; Post-Baccalaureate; Pre-doctoral; Postdoctoral; Faculty Levels)
- Instruction at Least Once During Each Career Stage
- Frequency: No Less Than Once Every Four Years
Frequency Continued

- Early Career (K Awards K-12): Once During This Stage
- Senior Fellows & Career Award (F33, K02, K05, K24): May Serve as RCR Lecturers & Discussion Leaders to Fulfill Requirements
- Instruction Must be Documented

Where in the Application Do You Address the RCR Components?

- Read the NIH Guidelines and Instructions
Limited 25 Pages

Organized Under Subheadings

Subheading #5: Responsible Conduct of Research

Responsible Conduct of Research*

Describe plans to provide formal and informal instruction to participants on scientific integrity and ethical principles in research. The plan should be appropriate for the duration and content of the proposed research education program. Although the NIH does not establish specific curricula or formal requirements, all programs are encouraged to consider instruction in the following areas: conflict of interest, responsible authorship, policies for handling misconduct, data management, data sharing, and policies regarding the use of human and animal subjects. Plans must address: 1) the subject matter of the instruction, the format of the instruction, the degree of program faculty participation, participant attendance, and the frequency of instruction; and 2) the rationale for the proposed plan of instruction.*


How May the RCR Instruction Plan Impact the Outcome of the Review?
“Applications Lacking a Plan for Instruction in Responsible Conduct of Research Will be Considered Incomplete and May be Delayed in the Review Process or Not Reviewed.”


Peer Reviewers Must:
- Evaluate Plans for RCR Instruction
- Address the 5 Instructional Components
- Be Guided by 6 Basic Principles
- If Applicable, Evaluate Past Record of Instruction (Renewal Application)

Peer Reviewers:
- Discuss Plan & If Applicable Past Record After Overall Determination is Met
- NOT a Factor in Determining Impact/Priority Score
Peer Reviewers Rate Plan as:

- Acceptable

Or

- Unacceptable

Peer Review

Unacceptable Plans

- Will Not be Funded

- Applicant Must Provide Acceptable Plan

- Institute or Center Staff Apply Six Principles to Determine if Revised Plan Acceptable

Sample

- R25 Application Submitted 2010
  Evers, Bernard Mark – Markey Cancer Center
  The University of Kentucky Cancer Nanotechnology Training Center (UK CNTC)
  Training in Responsible Conduct of Research (NIH R25)
What Information Must You Provide NIH if Funded?

- Reports Required
- Renewal – Application
- Documentation/Monitoring
- Effective January 1, 2011

Reporting Requirements: Continuation
Type 5 Institutional Training, Education, and Institute Development Awards – Must Describe:

- Nature of Instruction
- Extent of Trainee & Faculty Participation
- Any Changes to 5 Components from Plan Described in Awarded Application
- Specific Training Faculty Who Contributed to Formal Instruction Since Last Budget Period

Reporting Requirements – Continuation Type 5 Individual Fellowship – Must Report:

- Specific Instruction for Fellow
- Subject Matter
- Format
- Frequency
- Duration or
- When Training Did or Will Take Place
- Discuss Formal and/or Informal Activities
- Discuss Extent Sponsors or Senior Fellow Participated
Reporting: Continuation Type 5
Individual Career Development Awards –
Must Report:

- Instruction Received
- Participation as Course Director in Both Formal and Informal – Past Budget Period of Applicable
- If RCR Instruction Occurred Prior to Budget Period, Date of Occurrence
- Any Individualized Instruction Appropriate to Career Stage

Reporting Requirements Type 5 Continuation Dissertation Awards – Must Report:

- Include Separate Heading
- Describe Participation Formal and Informal RCR Instruction – Past Budget Period
- If Occurred Prior to Budget Period, List Date of Formal Instruction
- Any Individualized Instruction Appropriate to Career Stage
- Describe How Mentor Participated in Activities

Documentation/Monitoring

- Course Attendees Should be Monitored
- Certification or Documentation of Participation Should be Available at Course Completion
- Documentation Records Must be Made Available if Requested (Not Required to be Sent to NIH Unless Requested)
Resources: Federal and Associations

- NIH Research Training Website
  http://grants.nih.gov/training/extramural.htm
- DHHS Office of Research Integrity (ORI)
  http://ori.hhs.gov/
- “On Being a Scientist”
  http://www.nap.edu/catalog.php?record_id=12192

Resources: Federal

- Steneck, Nicholas, ORI, “Introduction to the Responsible Conduct of Research”, June 2004

Resources: University of Kentucky Web-Based

- Collaborative IRB Training Initiative (CITI) Instructions on ORI Website
- Includes RCR Modules: Biomedical, Social and Behavioral, Physical, Humanities, Engineering
CITI Module Topics

- Research Misconduct
- Data Acquisition, Management, Sharing and Ownership
- Publication Practices and Responsible Authorship
- Peer Review
- Mentor and Trainee Responsibilities
- Animal Welfare
- Conflicts of Interest and Commitment
- Collaborative Research
- Human Subjects

Resources: University of Kentucky Courses

- Ethical Issues in Clinical Research (3 cr) - PHR665/CPH 665 (Dr. Thomas Foster, instructor). Spring semester, offered every other year
- Ethics and Responsibility in Clinical Research (3 cr) – new course in development (Dr. William Stoops, instructor), will alternate every other spring with Ethical Issues in Clinical Research
- Ethics in Scientific Research (1 cr, typical) – TOX 600 (Dr. Isabel Mellon, instructor). Spring semester.

Resources: University of Kentucky Courses Continued

- Ethics in Clinical Sciences Research (1 cr) – CNU/NS 609 (Dr. Geza Bruckner, Instructor). Fall semester.
- Research Ethics and Dilemmas (3 cr) – BSC 776 (Dr. TK Logan, Instructor). Intermittent offering.
- There are ethics courses offered in specific academic areas, such as PSY 710, Ethical Issues in Clinical Psychology (3 cr.) – (Dr. Thomas Widiger, Instructor).
- College of Engineering RCR Initiative – Dr. Eric Grulke
Resources: UK Websites

- University of Kentucky Office of Research Integrity (ORI)
  http://www.research.uky.edu/ori/
- University of Kentucky Program for Bioethics
  http://ukhealthcare.uky.edu/bioethics/index.asp
- University of Kentucky Compliance Process (Interim Policy - NSF) – Office of Sponsored Projects Administration
  http://www.research.uky.edu/NSF_RCR_process.pdf

“Our Ethics Must Be As Good As Our Science”*

*Donna Shalala – Former HHS Secretary

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Questions?
Responsible Conduct of Research. All UK CNTC trainees will complete formal and informal training on the ethical conduct of research, ranging across such issues as human subjects safety and protections, use of animals in research, conflict of interest, responsible authorship, data management and confidentiality, data sharing, laboratory safety, and research misconduct. Training will combine online and face-to-face instruction to ensure training depth and synthesis. The UK Office of Research Integrity (ORI) maintains a comprehensive mandatory training series for all investigators and study personnel conducting research involving human subjects or animals, as described below. Certifications earned for completions of these courses will form a training basis; additional regulatory, compliance, and ethics training will be provided through UK’s Center for Clinical and Translational Science, which has combined classroom and distance learning offerings on a range of topics, including safe laboratory practice (e.g., chemical and biological safety) through the UK Division of Environmental Health and Safety.

Training and Certification in the Responsible Conduct of Human Research. Before observing or participating in research involving humans, trainees must complete UK’s required web-based training using one of two approved courses: Collaborative IRB Training Initiative (CITI) along with modules on Biomedical Responsible Conduct of Research and Good Clinical Practice or Dunn and Chadwick’s Protecting Study Volunteers in Training. Courses cover the rights and protection of human subjects, responsible use of human data, and ethical concerns for investigators involved in human studies. All trainees will also complete a web-based program in HIPAA Training, including basic training in regulations and reporting (Level 1) plus general training on patient privacy, restriction on use and disclosure of health information, amendment of patient records, and safeguards review (Level 2). In addition, trainees will receive direct instruction from their mentors in human research protections, including instruction/participation in preparing IRB applications and instructive modeling of the active implementation of the practices involved in the responsible conduct of research within mentor laboratories and clinical settings.

Training and Certification in the Responsible Use of Animals in Research. All trainees who conduct research using animals must complete the on-line course, The Humane Care and Use of Laboratory Animals administered by the Laboratory Animal Training Association, Inc. or IACUC 101 in the AALAS Learning Library available online through the ORI. These courses provide basic information on the care and handling of animals and the responsible conduct of animal research. Depending on the nature of their research, trainees may be required to complete additional online training modules, as determined by ORI staff and the IACUC. These courses complement, but do not substitute for, direct instruction in humane care and use of animals taught at the bench and modeled by example of the primary mentor.

Research Ethics Courses. Program participants will also be required to complete a formal semester-long course, choosing from those focusing variously on basic science or clinical research. Faculty mentors will advise participants in courses appropriate to the research focus. Two such courses are described below.

Ethical Issues in Clinical Research (PHR 665) is team-taught by UK leaders in research ethics, Jimmi Hatton, Pharm.D., Assoc. Professor, Pharmaceutical Sciences; Thomas Foster, Pharm.D., UK Medical IRB Chair; and Ada Sue Selwitz, M.A., ORI Director. This comprehensive semester-long course is a standard for training in research ethics at UK. The course focuses on 1) the practical application of ethical principles in the conduct of research through case study
and current literature and 2) ethical and regulatory considerations in the design, conduct, and publication of animal and human research. Topics include ethically sound study design; responsible conduct of research; regulatory and fiscal compliance; scientific misconduct; and ethical and regulatory implications of study designs involving vulnerable populations, tissue banking, and genetics/genomics to provide research integrity education and mentoring to trainees as individual investigators or interdisciplinary project team members.

**Ethics in Scientific Research (TOX 600)** is a semester-long course taught by experienced research faculty in the UK Graduate Center for Toxicology that covers such topics as good laboratory practice as the basis of good scientific research; quality assurance and appropriate practices in data selection, analysis, interpretation, and retention; the ethics of human and animal experimentation; and concepts of data and intellectual property, their ownership and access to them. Issues in reviewing others' intellectual property such as grant applications, research papers, and other intellectual property are also addressed.

**Mentor Faculty Expertise in Research Ethics.** UK training grant faculty maintain an especially high level of expertise in the responsible conduct of research. Within the College of Medicine, program directors of a number of T32 and Center of Biomedical Research Excellence (COBRE) grants coordinate a shared platform of supplemental instruction in research ethics. A seminar series led by Louis Hersh, PhD, Molecular and Cellular Biochemistry, and Thomas Garrity, PhD, Behavioral Science, provides for faculty-led instruction through an annual series of three to five face-to-face presentations for faculty and students supported by training and research education program grants. This schedule provides opportunities for ongoing instruction at ~two-month intervals. To enhance the certification and curricular offerings described above, UK CNTC faculty and students will participate in this initiative to facilitate shared ongoing training. Seminar topics repeat at intervals that are appropriate to the needs of incoming and established students and an appropriate training flow. Topics include conflict of interest, ethical obligations of authors, scientific misconduct, proper data management and sharing, and policies regarding human and animal studies. In addition to faculty instructors, guest speakers, who are typically UK leaders in research ethics, are also addressed.

**Regulatory and Research Ethics Advisor.** In her institutional role as a key leader in the field of research ethics and in UK's fully accredited human research protection program (Association for Accreditation of Human Research Protection Programs, Inc.), Ada Sue Selwitz, M.A., ORI Director and Co-director, Center for Clinical and Translational Science Regulatory Support and Research Ethics Core, will advise on emerging issues in research ethics and federal training requirements. Ms. Selwitz has maintained an active national presence, assisting in Federal policy development and consultation on issues of responsible conduct of research. She is extensively involved in training in the responsible conduct of research at local, regional, and national levels. She will consult on individual situations should questions or concerns arise in training or conduct of research.