

University of Kentucky			
Standard Operating Procedures			
Revision #	TITLE: Responsible Conduct of Research (RCR) Training		Page 1 of 5
Approved By: Vice President for Research	Signature:	Date:	Date First Effective: 03-18-2021

OBJECTIVE

To foster and promote ethical decision making, professionalism, best practices, and to ensure a baseline knowledge and understanding of fundamental ethical principles for the Responsible Conduct of Research (RCR).

GENERAL DESCRIPTION

On July 17, 2020, the Office of the Vice President for Research (OVPR) issued an email requiring RCR training. The mandatory RCR training applies to all full-time faculty, staff or trainees that participate in research or creative work. This includes staff supported in part or fully through research funding, grants and contracts, or who execute research and/or creative work, and trainees (undergraduates, graduate students, postdoctoral fellows, visiting scientists) participating in part or fully in research or creative work.

UK has partnered with the Collaborative Institutional Training Initiative (CITI) program to provide UK researchers online research ethics education that is part of the mandatory RCR training. The required online training consists of a 1 course instructional module and 6 substantive modules that cover:

- conflicts of interest
- mentoring
- data management
- reproducibility of research
- research misconduct
- peer review

Once basic training through completion of these modules is achieved the annual CITI RCR training requirement consists of primarily refresher modules.

In addition to the CITI RCR course, research personnel will be required to attend at least one in-person training course annually (described further below).

Definitions

Department of Health and Human Services (HHS)

Responsible Conduct of Research (RCR): Excerpt from Health & Human Services (HHS) Office of Research Integrity (ORI) book "ORI Introduction to the Responsible Conduct of Research" [\[PDF\]](#):

- Honesty: conveying information truthfully and honoring commitments,
- Accuracy: reporting findings precisely and taking care to avoid errors,

University of Kentucky		
Standard Operating Procedures		
Revision #	TITLE: Responsible Conduct of Research (RCR) Training	Page: 2 of 5

- Efficiency: using resources wisely and avoiding waste, and
- Objectivity: letting the facts speak for themselves and avoiding improper bias.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Research Personnel; Associate Deans for Research (ADRs)/Deans/Chairs/Unit Directors; OVPR staff; Office of Research Integrity (ORI) Staff; Office of Sponsored Projects Administration (OSPA) staff; Research Information Services (RIS) staff.

PROCEDURES

Training Completion Deadline

Basic or Refresher CITI RCR training requirements must be completed by eligible personnel annually. We will extend the requirement to complete the training for this inaugural year to May 31, 2021. If training is not completed and no exemption to the training issued, corrective action will be initiated.

The deadline for adhering to the in-person training requirement is (*to be determined based on CDC COVID-19 guidelines and the VPR Resumption of Research Plan*).

Frequency of Training

All full-time faculty, staff or trainees that participate in research or creative work are required to complete each training requirement on an annual basis.

Exemption to mandatory RCR training

Any UK employee or trainee who is designated to complete the online RCR training, but believe they should be exempt from the process, should submit, in writing, a justification to the Chair and/or Unit Director. The Chair and/or Unit Director should respond to the request with a determination, in writing.

If the Chair/Unit Director approves the request, the individual will complete the online [Exemption Request form](#). Once completed the individual will submit the form for decision through an institutional determination process.

The determination process includes via an ad hoc committee composed of members from the VPRs office, ORI, RIS and the ADR or Chair/Director from the unit where the request is originating. The ad hoc committee will interphase with college leadership in deliberating over exemptions. The frequency for meetings of the ad hoc committee will be monthly (if needed) followed by written dissemination of a decision to the individual and Chair/Unit Director.

If those requesting and/or approved for exemption from the training requirement are, or become, part of an Institutional Animal Care and Use Committee (IACUC) study, Institutional Review Board (IRB) study, or grant application, the exemption designation will be removed from the tracking software and the RCR training requirement will be enforced.

University of Kentucky		
Standard Operating Procedures		
Revision #	TITLE: Responsible Conduct of Research (RCR) Training	Page: 3 of 5

Tracking

RIS and the OVPR have created data models using SAP HANA employee and student data sources and OSPA records to create a list of individuals requiring RCR training. Online Tableau reports have been created that will be used by ORI, IACUC, and OSPA for central-level tracking. In addition, college-level personnel will have access to both summary level reports and detailed data for their own tracking purposes. These reports will be sent automatically to ADRs on a monthly basis. An automatic reminder email from CITI will be sent to individuals before their RCR training is due and the refresher course is required.

Process

1. The OVPR provides, to the College leadership (Dean, ADR, Chairs, Center Directors), a report of all personnel in their area required to complete the training and their current status each month. With this report will be a request to have personnel complete the basic or refresher training.
2. The ADR and Dean are responsible for:
 - a. promoting and informing all affected personnel of the requirement to complete the training;
 - b. working with Chairs/Unit Directors in assuring the training requirement is met;
 - c. if penalties are applied because of lack of adherence, assuring that penalties are enacted until training is completed.
3. Chairs/Unit Directors have primary responsibility for:
 - a. ensuring that personnel assigned to their unit complete the training by the stated final deadline;
 - b. communicating with their personnel once having received status reports;
 - c. providing, in writing, determinations on exemption requests and directing individuals to the online [exemption form](#);
 - d. when requested, participate as a member of the ad hoc committee to review exemption requests.
4. The OVPR maintains a report of all personnel who have completed training and their roles within the research infrastructure (e.g., personnel within IRB/IACUC protocol, personnel/staff on grants/contracts, etc.). OVPR also administers the determination process for exemption requests.

In-person Training and Departmental Participation

In addition to the CITI online RCR course, one in-person RCR training opportunity must be completed annually. In-person training will be made available through campus and departmental presentations. If preferred, researchers may schedule face-to-face RCR in-person instruction with ORI.

Faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal in-person instruction in RCR through a variety of modes as follows.

University of Kentucky		
Standard Operating Procedures		
Revision #	TITLE: Responsible Conduct of Research (RCR) Training	Page: 4 of 5

- Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year.
- Faculty may contribute to formal instruction in RCR as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal RCR courses over a period of time.
- Duration of in-person instruction: Instruction should involve substantive contact hours. **Acceptable programs generally involve at least two contact hours.** A semester-long series of seminars/programs may be more effective than a single seminar as topics will then be considered in sufficient depth and the subject matter synthesized within a broader conceptual framework.

To receive credit for these activities towards the required annual in person RCR training requirement, submit a brief description of the training session to vpr@uky.edu (subject heading “Annual RCR in person training”) for approval. Once an approved session has been conducted, submit a list of participants to rcr@uky.edu.

Potential Penalties

Personnel who have not completed or are not exempted from the RCR training requirement will have penalties applied. In addition, individuals who become eligible by participating in research, either as new employees, students, or those added to protocols and/or grants and contracts, are required to complete training within 30 days (i.e., training must be complete within 30 days after an individual’s payroll has been placed on a grant or contract).

Penalties will depend on the affected personnel and their role in research and could include any of the following:

- *Grants and contracts:* For new or non-competing project set-up, accounts will not be established unless the training requirement is completed.
- *IRB/IACUC protocols:* For PIs on protocols, submissions of new protocols will be returned to the PI until the RCR training requirement is met and/or untrained research personnel are removed, when appropriate, from protocols and/or sponsored project funding.
- *Access to institutional research funds:* Suspension of access to institutional funds for research, including use of start-up, access to pilot projects, creative activities funding, etc.
- *Other possible penalties include:*
 - Withholding salary
 - Withholding stipend
 - Not disseminating Facilities and Administration (F&A) monies

University of Kentucky		
Standard Operating Procedures		
Revision #	TITLE: Responsible Conduct of Research (RCR) Training	Page: 5 of 5

REFERENCES

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“Responsible Conduct of Research Training.” National Institutes of Health, U.S. Department of Health and Human Services, oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training.

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“Chapter IX Responsible Conduct of Research (RCR).” Proposal and Award Policies and Procedures Guide, 2019, pp. IX-3. OMB Control Number 3145-0058, www.nsf.gov/pubs/policydocs/pappg19_1/nsf19_1.pdf.

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