Best Practices and Lessons Learned from 30-Years of Teaching the "Responsible Conduct of Research" to Junior Faculty, Postdoctoral Scientists and Graduate/Undergraduate/High School Students at Columbia University

8th World Conference on Research Integrity

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Background

1989 NIH Notice: "first Notice of policy concerning instruction in responsible conduct of research…. required that institutional training grant applications include a description of activities related to instruction about responsible conduct of research"

NIH: National Institutes of Health - U.S. federal agency that is "the largest public funder of biomedical and behavioral research in the world"

Institutional training grants: Funding to support the research training of a cohort of graduate students, postdoctoral fellows, or both.

https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html
https://www.nih.gov/about-nih/what-we-do/impact-nih-research

REQUIREMENT FOR PROGRAMS ON THE RESPONSIBLE CONDUCT OF RESEARCH IN NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL TRAINING PROGRAMS

P.T. 44; K.W. 1014004, 1014006

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

A fundamental aspect of research is that it be conducted in an ethical and scientifically responsible manner. National Institutes of Health (NIH) and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) supported research training programs are notable for producing high quality researchers in the various fields of biomedical and behavioral science. Within this framework of excellence and relevance, it is important that attention be directed towards scientific integrity in the conduct of research.

Most universities and academic institutions have practices and procedures to ensure the responsible conduct of research. These may include informal seminars and presentations on conflict of interest, data recording and retention, professional standards and codes of conduct, responsible authorship, institutional policies and procedures for handling allegations of misconduct, policies regarding the use of human and animal subjects, etc. or formal courses on bioethics, research conduct, the ideals of science, etc.

To address this aspect of research training, the NIH and ADAMHA are revising the administrative guidelines for all National Research Service Award institutional training grants to require that a program in the principles of scientific integrity be an integral part of the proposed research training effort.

Effective July 1, 1990, all competing National Research Service Award institutional training grant applications must include a description of the formal or informal activities related to the instruction about the responsible conduct of research that will be incorporated into the proposed research training program.

https://grants.nih.gov/grants/guide/historical/1989_12_22_Vol_18_No_45.pdf

Background

1994 NIH Notice: "applications for institutional research training grants lacking a plan for instruction in responsible conduct of research be returned without review, established review procedures, and established the minimum requirements for an acceptable plan."

https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

REMINDER AND UPDATE: REQUIREMENT FOR INSTRUCTION IN THE RESPONSIBLECONDUCT OF RESEARCH IN NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL TRAINING GRANTS

NIH GUIDE, Volume 23, Number 23, June 17, 1994

o Although the NIH will not establish specific curriculum or format requirements, all programs are strongly encouraged to consider instruction in the following areas: conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, and data management.

https://grants.nih.gov/grants/guide/notice-files/not94-200.html

REMINDER AND UPDATE: REQUIREMENT FOR INSTRUCTION IN THE RESPONSIBLECONDUCT OF RESEARCH IN NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL TRAINING GRANTS

NIH GUIDE, Volume 23, Number 23, June 17, 1994

o Applications without plans for instruction in the responsible conduct of research will be considered incomplete and will be returned to the applicant without review.

https://grants.nih.gov/grants/guide/notice-files/not94-200.html

Course at Columbia University's Medical Campus

- Focus on the Responsible Conduct of Research (i.e., not just "misconduct")
- Curriculum: Rigorous and Comprehensive
- Scholarly and formal didactic program
- Formal for-credit course in the Graduate School of Arts & Sciences

Course at Columbia University's Medical Campus

- Required by degree-granting Programs
  - e.g., Doctoral, Master's
- Speakers are domain area experts
- Assigned readings, Suggested textbook
- Required scholarly paper on one of the topics addressed in the course (student's choice)
- Required in-person attendance

Course at Columbia University's Medical Campus

- Wide breadth of topics on the "Responsible Conduct of Research"
- Formal definition of the "misconduct of research" and institutional processes for addressing allegations is one of the topics
- Not a certification exercise

Update on the Requirement for Instruction in the Responsible Conduct of Research

Release Date: November 24, 2009

"**Similar requirements were subsequently adopted** for instruction via research education grants, individual fellowships, and career awards as funding opportunity announcements for these programs were published."

- Grad students and Post-docs supported by individual fellowships
- Junior faculty supported by career development awards
- High school, undergraduate and other students supported by short-term research training programs

https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

Update on the Requirement for Instruction in the Responsible Conduct of Research

Release Date: November 24, 2009

Instructional Components

1. **Format:** Substantial face-to-face discussions among the participating trainees/fellows/scholars/participants; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research are highly encouraged. **While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs (see below), or unusual and well-justified circumstances.**

https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

Update on the Requirement for Instruction in the Responsible Conduct of Research

Release Date: November 24, 2009

Instructional Components

2. **Subject Matter:** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

   a. conflict of interest – personal, professional, and financial
   b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
   c. mentor/mentee responsibilities and relationships
   d. collaborative research including collaborations with industry
   e. peer review
   f. data acquisition and laboratory tools; management, sharing and ownership
   g. research misconduct and policies for handling misconduct
   h. responsible authorship and publication
   i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

Update on the Requirement for Instruction in the Responsible Conduct of Research

Release Date: November 24, 2009

Instructional Components

3. **Faculty Participation:** Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in responsible conduct of research 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 responsible conduct of research courses over a period of time.

https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

Update on the Requirement for Instruction in the Responsible Conduct of Research

Release Date: November 24, 2009

Instructional Components

4. **Duration of Instruction:** Instruction should involve substantive contact hours between the trainees/fellows/scholars/participants and the participating faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

Update on the Requirement for Instruction in the Responsible Conduct of Research

Release Date: November 24, 2009

Instructional Components

5. **Frequency of Instruction:** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs and individual fellows/scholars are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Individuals at the early career investigator level (including mentored K awardees and K12 scholars) must receive instruction in responsible conduct of research at least once during this career stage. Senior fellows and career award recipients (including F33, K02, K05, and K24 awardees) may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the trainee, fellow or career award recipient is not actually supported by an NIH grant. This instruction can be documented as described below.

https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research

February 17, 2022

"new guidance on the format, frequency, and timing of RCR instruction, as well as additional topics for consideration."

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html

FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research

February 17, 2022

- **Format of Instruction**: Discussion-based instruction in the responsible conduct of research is expected to remain a key feature of RCR training and to include substantive face-to-face interaction among participants and faculty. However, recognizing that advances in video conferencing now allow for effective "face-to-face" discussions to occur electronically, institutions may wish to consider incorporating video conferencing options into their RCR instruction, provided that those options are utilized in a way that fosters discussion, active learning, engagement, and interaction among the participants. At the same time, video conferencing should not be the sole means for meeting the requirement for RCR instruction, and a plan that employs only video conferencing will not be considered acceptable, except in the circumstances described in NOT-OD-10-019, such as short-term research training and research education programs.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html

FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research

February 17, 2022

- **Frequency and Timing:** Existing policy and guidance call for RCR instruction to be undertaken at least once during each career stage, and at a frequency of no less than once every four years. As institutions consider how to optimize the timing and delivery of instruction in the responsible conduct of research, they are encouraged to bear in mind the value of ongoing and discipline-specific training as individuals progress in their research careers. For example, while broad-based instruction in the responsible conduct of research is often appropriate early in graduate school; a more tailored, discipline-specific approach may better fit the needs of advanced graduate students and those who have transitioned to postdoctoral status. If advanced students and postdoctorates have been exposed to the full range of topics traditionally included in RCR instruction early in their scientific training, it may make sense for their ongoing and/or subsequent RCR training to focus on subjects most relevant to their fields, and institutions may wish to consider this approach, where applicable.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html

FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research

February 17, 2022

- …at least once during each career stage,
- and at a frequency of no less than once every four years…
- ongoing and discipline-specific training as individuals progress in their research careers...
- broad-based instruction… early in graduate school…
- discipline-specific approach… advanced graduate students and those who have transitioned to postdoctoral status… RCR training to focus on subjects most relevant to their fields".

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html

FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research

February 17, 2022

- **Subject Matter**: Developments in the conduct of research and a growing understanding of the impact of the broader research environment have led to a recognition that additional topics merit inclusion in discussions of the responsible conduct of research. For context, those additional subjects appear in bold among the list of topics traditionally included in most acceptable plans for RCR instruction, cited in NOT-OD-10-019, and appearing below:

  a. conflict of interest – personal, professional, and financial – **and conflict of commitment, in allocating time, effort, or other research resources**
  b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
  c. mentor/mentee responsibilities and relationships
  d. **safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)**

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html

FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research

February 17, 2022

e. collaborative research, including collaborations with industry and **investigators and institutions in other countries**

f. peer review, **including the responsibility for maintaining confidentiality and security in peer review**

g. data acquisition **and analysis**; laboratory tools (**e.g., tools for analyzing data and creating or working with digital images**); **recordkeeping practices, including methods such as electronic laboratory notebooks**

h. **secure and ethical data use; data confidentiality**, management, sharing, and ownership

i. research misconduct and policies for handling misconduct

j. responsible authorship and publication

k. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html

Responsible Conduct of Research and Related Policy Issues

A Discussion of Scientific Research Ethics for Students, Post-doctoral Scientists and Fellows, and other Junior Investigators at the Columbia University Irving Medical Center

https://www.gsas.cuimc.columbia.edu/responsible-conduct-research-and-related-policy-issues

- "This course explores a variety of **ethical and policy issues** that arise during the conduct of basic, translational, epidemiological, and clinical biomedical research. The course's philosophy is to facilitate and encourage students to engage with Columbia faculty members who can speak from their own experience on ethical questions that can arise during the conduct of scientific research…
- The goal of the course is to **provide** students, post-doctoral scientists and fellows, junior faculty, and other investigators with **a knowledge base as well as practical advice** on ethical and policy issues."

https://www.gsas.cuimc.columbia.edu/responsible-conduct-research-and-related-policy-issues

- “Directors and Mentors of these pre-doctoral, postdoctoral, and junior faculty research training programs may wish to **augment the course** with additional requirements, including **small group discussion sessions**, or provide "refresher" training **involving individual training program faculty**.”

https://www.gsas.cuimc.columbia.edu/responsible-conduct-research-and-related-policy-issues

- Research misconduct, as well as policies and procedures for addressing
- Mentee-mentor relationship
- Authorship practices and scientific publications
- Research involving human participants/subjects
- Data acquisition, ownership, sharing, management, and reproducibility
- Use of laboratory animals in scientific research
- Conflicts of interest
- Peer review
- Intellectual property and technology transfer

https://www.gsas.cuimc.columbia.edu/responsible-conduct-research-and-related-policy-issues

- The role of scientists in society
- Collaborative research
- Partnerships with industry
- The scientific method
- Strategies for a successful research career
- Conflict of commitment
- Safe research environment
- Promoting inclusive excellence in STEM

Course sessions include lectures, class discussion, and case studies.

https://www.gsas.cuimc.columbia.edu/responsible-conduct-research-and-related-policy-issues

Responsible Conduct of Research and Related Policy Issues

Strengths and Challenges

- Diverse range of career levels
  - e.g., beginning Graduate Student to Junior Faculty
- Diverse range of research interests
  - e.g., Computational Biology to Clinical Trials

Responsible Conduct of Research and Related Policy Issues

Strengths and Challenges

- Participants from across the Medical Center
  - Vagelos College of Physicians and Surgeons, Mailman School of Public Health, School of Nursing, College of Dental Medicine, Ph.D. Programs in Biomedical Sciences
- Large class
  - Individual training programs should augment with small group sessions (specific for research area and career level)

https://www.gsas.cuimc.columbia.edu/responsible-conduct-research-and-related-policy-issues

Responsible Conduct of Research and Related Policy Issues

Strengths and Challenges

- Very busy class participants
  - e.g., Beginning graduate students juggling coursework and the early stages of their thesis research, junior clinical faculty juggling clinical responsibilities, research and didactics
- Required course

Responsible Conduct of Research and Related Policy Issues

- Students are concerned and very interested in these topics
- Their interest in these topics appears to be integrated with their research interests and activities and career goals

Responsible Conduct of Research and Related Policy Issues

- Their course essays are thoughtful and it is obvious they have spent time researching and writing their essays
  - Authorship: Credit
    - Who should be an author?
    - Order of names – Who should be 1st author?
  - Publications: Pressure to publish
    - Career Advancement
    - Journal (reputation, Impact Factor)
  - Mentorship, Supportive Research Training Environment
  - Research with Human Participants

Summary

- Recognizes that "substantial percentages of published results in some fields are not reproducible", and that there are "detrimental research practices" in addition to those that meet the formal definition of misconduct.
- "The research process goes beyond the actions of individual researchers… Research institutions, journals, scientific societies, and other parts of the research enterprise all can act in ways that either support or undermine integrity in research."

https://nap.nationalacademies.org/catalog/21896/fostering-integrity-in-research

Issues Related to the Conduct of Biomedical Research

- Research Misconduct
- Human Research Participants/Subjects
- Vertebrate Animals
- Authorship and Publication
- Peer Review
- Conflict of Interest
- Conflict of Commitment
- Credit/Recognition
- Data Ownership/Sharing/ Management
- Fetal/Embryo Research
- Rigor and Reproducibility
- Confidentiality
- Intellectual Property/ Technology Transfer
- Use of Biohazardous/rDNA/ Radioactive Materials
- Fiscal Management of Research Support
- Collaborative Science
- Dual Use Technologies/Dual Use Research of Concern
- Role of Foreign Governments/ Entities/ Influence
- Communication w/the Public
- Communication w/the Press
- Mentoring/Role Models
- Diversity & Inclusion