

**US Public Health Service (PHS) Policy on Instruction  
in the Responsible Conduct of Research (RCR)  
from the Office of Research Integrity**

## I. Introduction

Agencies of the Public Health Service (PHS) strongly believe in promoting the responsible conduct of research and preventing research misconduct, and other violations of responsible research, through education and awareness. Since 1990, NIH has required recipients of National Research Service Award research training grants to develop a program of instruction in the responsible conduct of research for trainees. With this policy, PHS extends the requirement to all staff at extramural institutions engaged in research or research training with PHS funds, or who work on PHS-supported research projects. A similar requirement will cover PHS intramural staff engaged in research or research training.

It is the view of the PHS that all researchers, from the inexperienced to the expert scientist, should be afforded educational opportunities that contribute to the development of the whole researcher and encourage the proliferation of life-long attitudes toward conducting research in a responsible manner. This document sets forth the terms of the PHS policy requiring RCR educational opportunities for all staff engaged in research or research training.

## II. General Policy

It is the policy of the PHS that all staff engaged in research or research training with PHS support shall successfully complete a program of instruction in the responsible conduct of research, as described in this document. The policy pertains to all research, including animal, human, or basic research, or research training, conducted with grant, contract, or cooperative agreement support from any agency, or office, of the PHS. Ensuring research integrity requires an institutional commitment. Although the mandatory aspects of this policy apply only to staff involved in research that is supported by PHS funds, it is strongly recommended that the program of instruction apply to all individuals engaged in research at the institution, including those supported by institutional, private, or other non-PHS sources of support.

## III. Definitions

"Program of Instruction" means completion of any educational activity, including a formal course, workshop, seminar, CD-ROM, Internet activity, self-study guide, discussion series, or other educational activity that is consistent with the goals and core areas of instruction outlined in this document.

"Institution" means the public or private entity or organization that is applying for, or is a recipient of, financial support from the PHS, including grants, contracts, or cooperative agreements. The organization assumes legal and financial accountability for the awarded funds and for the performance of the supported activity.

"RCR" means the responsible conduct of research.

#### IV. Scope

The policy applies to all staff who conduct research or receive research training with PHS funds, or who otherwise work on a PHS-supported research project even if the individual does not receive PHS support. "All staff" includes principal investigators, co-principal investigators, senior investigators, institutional officials who approve PHS grants, contracts, or cooperative agreements, tenure-track investigators, students, postdoctoral fellows, technicians, staff scientists, data management staff, subcontractors, consultants, clinicians, research nurses, research associates, research assistants and anyone else involved in conducting the research or who receives research training at the institution, or under the direction of the institution. PHS recommends that departmental and sponsored research staff, secretarial, and other support staff receive instruction in RCR relevant to their jobs and roles in the research enterprise. This does not limit the authority of the institution to impose more detailed or broader requirements for RCR education on research staff.

#### V. Instructional Program Goals

- A. The goals of the PHS-required RCR program of instruction are to:
1. Increase knowledge of, and sensitivity to, issues surrounding the responsible conduct of research and research misconduct.
  2. Improve the ability of participants to make legal and ethical choices in the face of conflicts involving scientific research.
  3. Develop an appreciation for accepted, normative scientific practices for conducting research.
  4. Provide information about the regulations, policies, statutes, and guidelines that govern the conduct of research in PHS funded institutions.
  5. Provide resources for additional study on topics related to scientific integrity, responsible conduct of research, and research misconduct.
  6. Develop a positive attitude toward life long learning in matters involving the responsible conduct of research.
- B. The institution may adopt additional goals consistent with the PHS goals.

#### VI. Core Instructional Areas

- A. To the extent applicable to the research programs at the institution, any RCR program of instruction shall contain the following core areas of instruction:
1. Data acquisition, management, sharing, and ownership
  2. Mentor/trainee responsibilities
  3. Publication practices and responsible authorship
  4. Peer review
  5. Collaborative science
  6. Human subjects
  7. Research involving animals
  8. Research misconduct

9. Conflict of interest and commitment
10. Compliance with existing PHS and institutional policies

B. Responsibility for determining whether to require a demonstration of competency in the core areas rests with the institution. However, PHS recommends that any program of instruction contain practice and evaluative components to reinforce learning and attitudes, practice new skills, and test for information transfer.

## VII. Description of Core Instructional Areas

The Core Instructional Areas are described as follows:

### 1. Data acquisition, management, sharing, and ownership

Accepted practices for acquiring and maintaining research data. Proper methods for record keeping and electronic data collection and storage in scientific research. Includes defining what constitutes data: keeping data notebooks; data selection, retention, sharing, ownership, and analysis; data as legal documents and intellectual property, including copyright laws.

### 2. Mentor/trainee relationships

The responsibilities of mentors and trainees in predoctoral and postdoctoral research programs. Includes the role of a mentor, responsibilities of a mentor, conflicts between mentor and trainee, collaboration and competition, selection of a mentor, and abusing the mentor/trainee relationship.

### 3. Publication practices and responsible authorship

The purpose and importance of scientific publication, and the responsibilities of the authors. Includes topics such as collaborative work and assigning appropriate credit, acknowledgements, appropriate citations, repetitive publications, fragmentary publication, sufficient description of methods, corrections and retractions, conventions for deciding upon authors, authors' responsibilities, and the pressure to publish.

### 4. Peer review

The purpose of peer review in determining merit for research funding and publications. Includes topics such as, the definition of peer review, impartiality, how peer review works, editorial boards and ad hoc reviewers, responsibilities of the reviewers, privileged information and confidentiality.

### 5. Collaborative science

Research collaborations and issues that may arise from such collaborations. Includes topics such as setting ground rules early in the collaboration, avoiding authorship disputes, and the sharing of materials and information with internal and external collaborating scientists.

### 6. Human subjects

Issues important in conducting research involving human subjects. Includes topics such as the definition of human subjects research, ethical principles for conducting human subjects research, informed consent, confidentiality and privacy of data and patient records, risks

and benefits, preparation of a research protocol, institutional review boards, adherence to study protocol, proper conduct of the study, and gender, minority, and children's research issues.

#### 7. Research Involving Animals<sup>2</sup>

Issues important to conducting research involving animals. Includes topics such as definition of research involving animals, ethical principles for conducting research on animals, federal regulations governing animal research, institutional animal care and use committees, and treatment of animals.

#### 8. Research misconduct

The meaning of research misconduct and the regulations, policies, and guidelines that govern research misconduct in PHS-funded institutions. Includes topics such as fabrication, falsification, and plagiarism; error vs. intentional misconduct: institutional misconduct policies, identifying misconduct; procedures for reporting misconduct; protection or whistleblowers: and outcomes of investigations, including institutional and federal actions.

#### 9. Conflict of Interest and Commitment

The definition of conflicts of interest and how to handle conflicts of interest. Types of conflicts encountered by researchers and institutions. Includes topics such as conflicts associated with collaborators, publication, financial conflicts, obligations to other constituencies, and other types of conflicts.

#### 10. Compliance with existing PHS and institutional policies

Identification and understanding of existing federal and local policies, methods of compliance, and consequences for not complying.

### VIII. Instructional Models and RCR Resources

A. This policy does not establish specific instructional format or program length requirements.

Acceptable models currently established at some institutions include:

1. Completing the modules and exams on a CD-ROM or in a self-study booklet
2. Attending a one-credit academic course
3. Attending a workshop
4. Attending a series of lectures

B. Internet resources for locating RCR related educational materials and answering questions about the RCR policy implementation will be announced at the time of policy publication.

### IX. Phase-in Period and Implementation

A. phase-in period of two years from the policy's publication date has been established for program implementation to allow current research staff to receive the program of instruction. Currently, all research staff at the institution, as specified in the Scope of this policy, are required to have completed a program of instruction in RCR, as described.

B. New staff shall complete a program of instruction in RCR within one year of beginning work on the research. The one-year grace period should be sufficient to accommodate institutions in which the RCR instruction is offered only once a year. In the event that a newly hired individual has previously completed timely instruction that meets the requirements of any of the core instructional areas as outlined in the policy, that person may receive credit for that portion of the program of instruction that was completed. In addition, persons who have completed timely instruction that meets the requirement for any of the core instructional areas outlined in the policy, prior to the implementation of the policy, will not be required to repeat that portion of the instruction that was completed.

C. It is strongly recommended that all research staff receive periodic, continuing education, e.g. an annual film, discussion, short seminar, etc. in RCR to refresh and extend knowledge of RCR issues, keep current on updates and new policies, and maintain sensitivity to the issues.

D. From time to time, the PHS may publish a notice of amendment to this policy making a material addition to the Core Instructional Areas of the RCR requirement or materially modifying the subject-matter Description of any Core Instructional Area, including, but not limited to the adoption of new regulations, policies or procedures affecting the responsible conduct of research. Such notice will denominate such change to the RCR requirement as a "Material Change." Within six (6) months after the publication of the Federal Register notice announcing a Material Change, all extramural institutions subject to the RCR requirement shall revise their written program of instruction in conformance with the notice and ensure that all new staff complete a program of instruction in RCR that reflects the Material Change. In addition, said extramural institutions shall provide training on the Material Change to all staff previously trained in the RCR within twelve (12) months of the publication of the notice.

## X. Accountability and Reporting

A. Each institution that applies for or receives PHS funds for research or research training, beginning on October 1, 2000, must certify that:

1. The institution will establish a program of instruction that meets the requirements of this policy and a written description documenting the program by June 1, 2001. In addition to addressing the requirements of this policy and its applicability to all PHS-supported staff and those working on PHS-supported research projects, this description must address how, or whether, the program is being applied to those research staff not supported by PHS funds.
2. The institution will publish the written description of the program of instruction or otherwise make it accessible to research staff at the institution or working under the direction of the institution.
2. The institution will carry out its program of instruction.
4. Initial implementation of the program of instruction, for existing staff, will be completed by October 1, 2002.

B. The RCR instruction certification will be conducted in conjunction with the current Assurances/Certifications on the grant application, Form PHS 398, and in conjunction with the submission of the Annual Report on Possible Research Misconduct (Form 6349) by institutions, to the Office of Research Integrity (ORI). Compliance for work conducted under contracts will be assured under a different mechanism. ORI may ask institutions to submit, for review, a written description of their RCR program of instruction, at any time.

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On June 5, 2000, NIH announced in the NIH Guide new requirements for education in the protection of human subjects, beginning on October 1, 2000. Once the PHS Policy on Instruction in the Responsible Conduct of Research is fully implemented (See Section IX), it will supersede the NIH policy for purposes of this core requirement. There will be a subsequent announcement when this occurs. In addition, the Office for Human Research Protections is developing further guidance on instruction for responsible research in human subjects for institutions and individuals actually conducting such research. This policy will be updated as appropriate when that guidance is available.

The PHS Policy on Instruction in the Responsible Conduct of Research complements, but does not supersede, the existing instructional requirements of the PHS Policy on Humane Care and Use of Laboratory Animals and the NIH Office of Laboratory Animal Welfare. Individuals who receive instruction in compliance with these latter requirements will also be deemed in compliance with core element 7 (Research Involving Animals) of this policy.