

December 1, 2000

## PHS Policy on Instruction in the Responsible Conduct of Research (RCR)

### I. Background and Introduction

The Public Health Service (PHS) has been addressing for more than a decade recommendations from the research community to further a joint commitment to education in the responsible conduct of research. In 1989, the Institute of Medicine (IOM) stated that “instruction in the standards and ethics of research is essential to the proper education of scientists,” and recommended that “[u]niversities ... provide formal instruction in good research practices.”<sup>1</sup> In that same year, the PHS published misconduct regulations that state that research “[i]nstitutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested.”<sup>2</sup> In 1990, the National Institutes of Health required all applications for National Research Service Award Institutional Training Grants to include a description of a program to provide instruction in the responsible conduct of research. In 1992, the National Academy of Sciences expanded and repeated IOM’s earlier recommendation by stating that “[s]cientists and research institutions should integrate into their curricula educational programs that foster faculty and student awareness of concerns related to the integrity of the research process.”<sup>3</sup> The Commission on Research Integrity recommended in 1995 that the Department of Health and Human Services add a new assurance “that the institution has an educational program on the responsible conduct of research ... [that] applied to all individuals supported by PHS research funds.”<sup>4</sup>

These actions by the PHS and research community over the past decade have produced substantial strides by research institutions, scientific societies and associations, individual scientists, and government agencies in providing increased awareness of and formal instruction in the responsible conduct of research. However, more can be done at the Federal and

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<sup>1</sup> *The Responsible Conduct of Research in the Health Sciences*, p. 30 (IOM 1989).

<sup>2</sup> 42 CFR 50.105.

<sup>3</sup> *Responsible Science: Ensuring the Integrity of the Research Process*, p. 13 (NAS 1992).

<sup>4</sup> *Integrity and Misconduct in Research*, p.18 (HHS 1995).

institutional levels to promote responsible research practices in protecting human subjects, monitoring potential conflicts of interest, and in other areas. Accordingly, the PHS announces adoption of this policy to recognize accomplishments to date and to stimulate greater efforts and cooperation between the PHS and the research community in providing instruction in the responsible conduct of research. A similar policy will cover PHS intramural staff engaged in research or research training.

## II. General Policy and Scope

- A. It is the policy of the PHS that research staff (as defined below) at extramural institutions shall complete a basic program of instruction in the responsible conduct of research, as set forth in this document. Research staff who are working on the PHS-supported project at entities other than the institution that received the PHS research grant, cooperative agreement, or contract, are also covered by the policy. The institution may make reasonable determinations as to which research staff fall within the policy. The policy pertains to all research, including animal, human, and basic research, or research training, conducted with grant, contract, or cooperative agreement support from any agency, or office, of the PHS.
- B. The PHS also recommends, but does not require, that the institution consider the need for providing RCR instruction to (1) non PHS-supported research staff at the institution, including those supported by institutional, private, and other governmental sources of support and (2) departmental and sponsored research/administrative staff and other support staff, with instruction relevant to their jobs and roles in the research enterprise (as determined by the institution). This policy does not limit the authority of the institution to expand the policy's scope or to impose broader requirements for RCR education.

## III. Definitions

“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.

“Instruction/Program of Instruction” means completion of an educational activity, such as reading a self-study guide; attending a lecture, formal course, workshop, or seminar; making a presentation; working through a CD-ROM or Internet program; leading or participating in a discussion of case studies; or participating in any other educational activity that is consistent with the terms of the policy.

“RCR” means the responsible conduct of research.

“Research staff” means staff at the institution who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training, supported by PHS funds or who otherwise work on the PHS-supported research project even if the individual does not receive PHS support. The institution may make reasonable determinations regarding which research staff fall within this definition.

#### IV. Purpose and Basic Principles

- A. This document explains the PHS policy on education in the responsible conduct of research for staff engaged in PHS supported research. PHS agencies and research institutions strongly believe in promoting the responsible conduct of research and discouraging research misconduct and questionable research practices through education and awareness. With this policy, PHS extends the existing NIH educational requirement for research trainees to all research staff at extramural institutions who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training, supported by PHS funds or who otherwise work on PHS-supported research projects even if the individual does not receive PHS support.
- B. This policy reflects the following underlying principles.
  1. The PHS and research institutions recognize the importance of providing instruction in the responsible conduct of research to PHS-supported researchers. While this policy only requires basic instruction, the long-term goal of providing high quality, relevant instruction appropriate to the needs of the individual researcher may involve more detailed and specific instruction that can be phased-in over time as new curricula materials and methods of instruction are developed and as the needs of the research institution dictate.
  2. Institutions are given flexibility to determine the exact content, length, level, and method of instruction consistent with this policy. They may use available resources, develop their own resources, and determine whether or not to require a demonstration of competency by recipients of the instruction. The PHS will make available educational resources that will assist institutions to meet the policy as described in Section VI.
  3. The institution may reasonably determine which “research staff” fall within the scope of this policy.
  4. Instruction in the core areas is required to the extent that the core areas are applicable to the institution’s research programs and the particular research projects and staff involved. The institution may exercise reasonable

discretion in determining which core areas are applicable to its research staff.

5. The institution may determine the method of documenting that instruction has occurred.

C. The policy reflects the importance that the PHS places on fundamental and continuing education in conducting research responsibly, and it provides a basic foundation from which more detailed or focused programs may develop. Through this policy, PHS seeks to join with research institutions and researchers to pursue the following long-term goals:

- Increase knowledge of, and sensitivity to, issues surrounding the responsible conduct of research.
- Improve the ability of participants to make ethical and legal choices in the face of conflicts involving scientific research.
- Develop appreciation for the range of accepted scientific practices for conducting research.
- Provide information about the regulations, policies, statutes, and guidelines that govern the conduct of PHS-funded research.
- Develop positive attitudes toward life-long learning in matters involving the responsible conduct of research.

Moreover, the PHS is committed to providing educational resources that meet the requirements of this policy and financial resources to further the development of educational products in the responsible conduct of research.

## V. Core Instructional Areas

A. The policy includes instruction in nine core areas determined by the PHS to be significant in conducting responsible research and ensuring integrity of the research record. Some institutions may decide that all research staff covered by the policy should receive some exposure to each of the core areas, even if at a very basic level, such as reading an overview or attending a brief presentation, in order to ensure that all research staff have received a well-rounded RCR education. However, the PHS recognizes that not all of the core areas are applicable to the research programs at every institution. Therefore, the institution may exercise reasonable discretion in determining which core areas are applicable to the research staff receiving instruction at the institution. The core instructional areas are:

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<sup>5</sup>
7. Research involving animals<sup>6</sup>
8. Research misconduct
9. Conflict of interest and commitment

- B. For each of the nine core areas, information about compliance with related PHS and institutional policies should be included in the instruction provided. The Appendix to this policy contains descriptions and possible topics for the core instructional areas. It is intended as guidance material only and is not a detailed list of prescribed topics for each core area. Responsibility for determining whether to require a demonstration of competency in any of the core areas rests with the institution.

## VI. RCR Instructional Resources

This policy does not establish exact content or minimum length, level, or format of instruction. The determination of the content, length, level, and format of instruction rests with the institution. However, in order to provide assistance to research institutions, PHS is committed to providing RCR educational resources that meet the policy, providing financial resources for broader development of RCR materials, and encouraging the sharing and centralization of

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<sup>5</sup> On June 5, 2000, NIH announced in the *NIH Guide for Grants and Contracts* 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 VII), 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 of Human Research Protections (OHRP) plans to provide further guidance on instruction for responsible research in human subjects in the next several months. Individuals who receive instruction in compliance with this OHRP guidance will also be deemed in compliance with core element 6 (human subjects) of this policy.

<sup>6</sup> 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.

existing RCR educational resources. For current information on available RCR resources, check the Office of Research Integrity (ORI) web site at <<http://ori.hhs.gov>>.

## VII. Phase-in Period and Implementation

- A. A phase-in period has been established for program implementation to allow current research staff to receive the program of instruction. By October 1, 2003, all research staff at the institution, as specified in the policy and reasonably determined by the institution, shall have received a program of instruction in RCR, as described.
- B. New research staff beginning work after October 1, 2003, shall receive instruction in RCR prior to working on a research project, or as soon thereafter as practicable, but no later than one year after beginning work on the research project.<sup>7</sup> In the event that a newly-hired individual has previously completed timely instruction in any of the core instructional areas described 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, prior to the implementation of the policy, will not be required to repeat that portion of the instruction that was completed.
- C. It is recommended that all research staff covered by the policy receive periodic, continuing education, e.g., videos, group discussion, short seminar, newsletters, etc., in RCR to refresh and extend knowledge of RCR issues, keep current on updates and new policies, and maintain sensitivity to the issues.

## VIII. Assurances

- A. Each institution that applies for or receives PHS funds for research or research training must assure by October 1, 2001, that:
  - 1. The institution has a program of instruction that complies with this policy and has a written description documenting the program. The written description must address the provisions of this policy, its applicability to all research staff at the institution, and how the institution plans to document completion of RCR instruction by its research staff. The institution may include in its written plan a description of the role it

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<sup>7</sup> Researchers involved in human subject or animal research may be subject to separate educational provisions which require that instruction be received prior to working on projects involving human or animal subjects.

expects the principal investigator to play in assisting the institution to implement the policy. Defined roles of principal investigators in this context will augment, but not supplant, the responsibility of the institution to provide RCR instruction as required. ORI may ask an institution to submit the written description of its RCR program of instruction at any time.

2. The institution will publish, or otherwise make accessible, the written description of the program of instruction to research staff at the institution and to others who work on the PHS-supported research project.
  3. The institution will carry out its program of instruction.
  4. Implementation of the institution's program of instruction for existing staff will be completed by October 1, 2003.
- B. The RCR instruction assurance will be provided in conjunction with the 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. Compliance for work conducted under contracts will be assured under a different mechanism.

## APPENDIX: Description of Core Instructional Areas

PHS provides as guidance the following description of the Core Instructional Areas:

### **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 or electronic files; data privacy and confidentiality; 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, acknowledgments, appropriate citations, repetitive publications, fragmentary publication, sufficient description of methods, corrections and retractions, conventions for deciding upon authors, author 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 special protections for targeted populations, e.g., children, minorities, and the elderly.

## **7. Research Involving Animals**

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 of 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.