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Frequently Asked Questions for the PHS Policy on Instruction in the Responsible Conduct of Research (RCR)

1. Are research staff who are not part of the institution, but working on the research project for the institution required to have this instruction (e.g., subcontractors and consultants)?

Answer: Yes, if they meet the definition of research staff as outlined in the Scope of the policy, then the policy applies to them.

2. Does the PHS policy apply to non-PHS supported research?

Answer: No, the policy does not require that research staff working on non-PHS research projects receive RCR instruction, but PHS does recommend that the institution consider providing such instruction.

3. Do research staff on foreign awards or on foreign subcontracts have to comply with this policy?

Answer: Yes, this policy applies to all research staff involved in research supported by PHS funds, including foreign awardees and foreign collaborators and sub-contractors.

4. What does the policy mean by stating that institutions may make “reasonable determinations” regarding which research staff fall within the scope of the policy?

Answer: The PHS policy covers staff who have “direct and substantive involvement in proposing, performing, reviewing, or reporting research” or who receive research training. This includes staff such as the PI and co-investigators who write the grant application, conduct the actual research, and report the research in abstracts, articles, and at scientific and lab meetings. For many staff, the decision of whether they fall within the scope of the policy will depend on their actual role in the research, not their title. This is an area where an institution may make reasonable determinations regarding which research staff are covered by the policy. For example, an institution may decide that an experienced technician who actually conducts the experiments is covered by the policy even if other, less experienced technicians with a lesser role are not.

5. What does it mean that the institution may exercise “reasonable discretion” in

determining the degree of applicability of the core areas?

Answer: If research staff have no involvement with human subject or animal research, or mentoring, for example, then that staff do not need to receive instruction in those core areas. However, PHS recommends that the institution consider providing a basic level of instruction in all the core areas for research staff covered by the policy.

6. How can RCR instruction be provided to foreign research staff who do not understand English and, thus, cannot use RCR curricula materials developed by PHS or U.S. based institutions?

Answer: In some cases, it may be possible to have the RCR materials translated into the native language of the foreign research staff. If that is not possible, virtually every foreign awardee, sub-contractor, or collaborator must have someone capable of communicating with the domestic U.S. institution (in case of a collaboration or sub-contract) or the PHS grantor agency (in case of a foreign award). Thus, it should be possible to use this person, perhaps in conjunction with the foreign PI or key research staff, to provide the RCR instruction to the foreign site.

7. Does the institution have to send a written description of their plan for instruction to ORI by October 1, 2001?

Answer: No. The policy states that the institution will establish a program of instruction and a written description of the program of instruction by October 1, 2001. Institutions will not be asked to send the descriptions to ORI at that time. Each year, ORI will choose a sample of institutions and ask them to submit their written descriptions for review. In addition, ORI will check on the status of institutional plans by asking for information in its Annual Report on Possible Research Misconduct which is submitted to those institutions which have an ORI misconduct assurance (form PHS-6349). This form will be modified to include a question on the availability of institutional RCR plans and responses to this question will be first collected in early 2002 as part of the Annual Report process.

8. What is meant by “timely training” in determining credit for people who have already had RCR instruction previously or at another institution?

Answer: Education in RCR received in the past few years will generally be considered timely. However, instruction received many years ago prior to major regulatory changes would not be considered timely. For example, the PHS conflict of interest regulation, 42 CFR Part 50, Subpart F, was adopted in 1995. Thus, education in the core area of conflict of interest and commitment prior to 1995 would not be considered timely.

9. What funding/grants/educational resources are available that can help institutions meet the needs of the required training?

Answer: Many institutions have already begun developing educational programs on the responsible conduct of research. ORI is presently supporting development of educational products that comply with the policy and encourages the sharing and centralization of RCR instructional resources.

With support from ORI, a web site entitled The Online Resource for Instruction in the Responsible Conduct of Research was developed at UC-San Diego. The web site is a comprehensive site that contains instructional resources, cases, useful links, instructional tools and other useful information for instruction in RCR. Visit the web site at <http://rcr.ucsd.edu/>.

In another effort, ORI has contracted with an experienced research ethics instructor to develop a self-instruction booklet that will cover the core instructional areas listed in the RCR policy. The booklet is being developed primarily for small and mid-sized institutions, but could be used by any institution. It is scheduled to be completed by May 2001. In addition, ORI is working with NIH and other PHS agencies to provide funding for the creation of additional RCR resources through the SBIR/STTR programs. A program announcement is expected by January 2001.

Additional web sites (not all inclusive) with useful RCR information include the University of Minnesota web site at <http://www.research.umn.edu/ethics/> and the Virginia Commonwealth University web page on Scientific Integrity at <http://views.vcu.edu.808/mic510a/>. Opportunities for future funding will be announced on the ORI web site at <http://ori.dhhs.gov> in addition to the standard announcement mechanisms. Also, consult the ORI web site for links to additional sources of RCR educational programs and instructional materials.

10. What will ORI do if an institution doesn't have an RCR education program?

Answer: ORI will notify the institution of its non-compliance status and provide an opportunity for the institution to take corrective action. ORI will also offer technical assistance if the institution is unsure how to establish a program. At that point, if the institution is still out of compliance, ORI will inactivate the institution's assurance making it ineligible to receive PHS research or research training funds.

11. What will happen if an institution has an “inadequate” program of instruction.

Answer: The PHS policy provides a great deal of flexibility to institutions in implementing the policy. Thus, it is not expected that ORI will be faced with an inadequate program frequently. However, if an institution fails to comply with the few requirements of the policy, such as making all instruction optional instead of mandatory or not requiring education in certain core areas when they clearly apply, ORI will handle the non-compliance similarly to the question above where an institution has no education program. ORI will provide the institution with notice and an opportunity to take appropriate corrective action before taking any enforcement action. ORI will also offer technical assistance to make sure the institution is aware of how to provide an adequate education program.

12. Is a CD-ROM of three hours in length enough to meet the requirements of the policy?

Answer: Yes. In fact, that is the expected length of ORI’s booklet/web module that is currently being developed. However, many experienced RCR instructors recommend supplementing written materials, CD-ROMS, and other self-instructional methods with interactive case discussions.

13. Are institutions required to develop an education program, or can it be contracted out? Can ready made off-the-shelf instructional packages be used?

Answer: Yes, the institution’s RCR program can be contracted out or off the shelf materials can be used if they meet the basic requirements of the policy and serve the needs of the institution.

14. If an institution already has an approved Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW) are there additional steps needed to satisfy the core instructional area of research involving animals (core element #7) in the RCR Policy?

Answer: No. Institutions with approved Animal Welfare Assurances have demonstrated compliance with the PHS Policy on Humane Care and Use of Laboratory Animals, as determined by OLAW, and will therefore be in full compliance with the research involving animals core instructional area of the RCR policy.

15. What role does the Principal Investigator (PI) have in providing RCR instruction under the policy?

Answer: Although the policy does not require any formal role for the PI in providing instruction required under the policy, many institutions will expect the PI to assist in implementation in a variety of roles, such as an instructor in RCR education programs, reinforcing principles learned by laboratory staff during instruction, holding a lab meeting to discuss case studies, determining which research staff fall under the policy, and documenting that research staff have received instruction. Although not required by

the policy, some institutions may choose to add a formal role for the PI in implementing the policy in the written plan of instruction required by section VIII. Doing so, however, will not supplant the institutional responsibility to ensure that RCR instruction is provided in compliance with the policy.

16. I understand that the Office of Human Research Protections (OHRP) will be providing its own guidance on the type of education it expects for investigators who conduct research on human subjects. Will that mean that institutions will have to comply with two separate requirements, one for ORI and a different one for OHRP.

Answer: No. Any institution which provides an education program in compliance with OHRP policy will be considered to have met the requirements of core element #6 (human subjects) of this policy.

17. Does a PHS-supported scientist who participates in providing RCR instruction also have to be a recipient of such instruction in order for the institution to be in compliance with the RCR policy?

Answer: No. A scientist who provides instruction in RCR is assumed to have obtained sufficient knowledge and awareness of the core elements of RCR to have met the requirement of the policy. In this regard, the policy has been revised to include “making a presentation” or “leading ... a discussion of case studies” in the definition of completion of an educational activity under a “program of instruction.”