

Federal Government Imposes Training Requirements on Researchers

In separate actions, two agencies of the federal government have imposed new training requirements on researchers receiving federal funds. On June 5, 2000, the National Institutes of Health (NIH) issued a policy that mandates education regarding the protection of human subjects for all investigators submitting proposals for NIH grants or contracts. The effective date of this policy was October 1, 2000. Therefore, before funds will be awarded by NIH for proposals involving the use of human subjects, the investigator must provide a description of the education program completed by all persons identified as “key personnel” in the proposed research.

Fortunately, NIH has provided a resource for meeting this requirement. An on-line tutorial may be completed by logging on to the NIH website at <http://ohsr.od.nih.gov/cbt>. At the completion of this tutorial the investigator will receive a certificate that can be submitted along with the grant or contract application in satisfaction of the education requirement. In addition, the University of Rochester has made its training program available through Centerwatch, Inc. (<http://www.centerwatch.com>). It is important to note that this policy only applies to NIH proposals that involve the use of human subjects. It does not apply to other types of research involving other federal agencies.

The limited applicability of this education requirement will only remain in place until October 1, 2001, however. On that date, under a new policy issued by the Office of Research Integrity (ORI), each institution that receives funding from the Public Health Service (PHS) must give assurance that it has a program of instruction in the responsible conduct of research. This 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. In addition, the PHS recommends that such instruction also be given to non-PHS supported research staff.

The policy identifies nine core areas of instruction: data acquisition, management, sharing, and ownership; mentor/trainee responsibilities; publication practices and responsible authorship; peer review; collaborative science; human subjects; research involving animals; research misconduct; and conflict of interest and commitment. With respect to instruction concerning the use of human subjects, the PHS policy will supercede the NIH policy mentioned above. This instruction program must be provided to covered research staff by October 1, 2003.

Each institution has the discretion to determine the content, length, level, and method of instruction. Identifying the research staff that are subject to this policy and deciding which core areas of instruction are applicable to each staff member are also decisions left to the institution. The method of instruction can take any one of several forms, including reading a self-study guide; attending a lecture, formal course, seminar, or workshop; working through a CD-ROM or Internet program; or any other educational activity reasonably designed to achieve the purposes of the policy. ORI expects to provide materials that will satisfy the policy.

These policies create another substantial administrative burden on both the institution and the individual investigator. Although it is difficult to dispute the underlying objective of these policies, once again the federal government has mandated a program without providing the funding to implement it. Even though the level of PHS-funded research at UAH is relatively low, the University will nevertheless be required to fully comply with this policy to remain eligible for funding for those proposals that are submitted to PHS. Therefore, faculty and staff involved in funded research can expect to hear more about the implementation of this policy in the coming months.