

Report to the AAPOR Standards Committee on the status of Human  
Subjects Protection Training Requirements  
May 16, 2009

BACKGROUND

In June 2000 the NIH released NOT-OD-00-039: REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS. This notice (revised 8/25/00) essentially stated that starting October 1, 2000, the NIH would require human subjects protection (HSP) training for all “key personnel” on proposals for any NIH funding. While the implications of this for clinical researchers was reasonably clear, nine years later there is still uncertainty among social and behavioral researchers about who must receive HSP training, especially those who use survey research to collect data from human subjects.

WHO IS COVERED?

The notice of this new rule (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>) stated that “Before funds are awarded for competing applications or contract proposals involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as “key personnel” in the proposed research. Key personnel include all individuals responsible for the design and conduct of the study.” It is very clear that “key personnel” included Principal Investigators and other senior scientific staff on a proposal, but nine years later there is still ambiguity about who else may be considered key personnel, especially for survey researchers. In particular, does this include interviewing staff who have no role in the “design” of the research, but indeed are intimately involved in the “conduct” of the research.

In an attempt to clarify questions about who must be trained and what constitutes training, the NIH released an FAQ in 2008, Frequently Asked Questions for the Requirement for Education on the Protection of Human Subjects (updated 9/10/2008) ([http://grants.nih.gov/grants/policy/hs\\_educ\\_faq.htm](http://grants.nih.gov/grants/policy/hs_educ_faq.htm)). However, on the question of who constitutes key personnel they essentially re-state the original notice: “Individuals who will be involved in the design or conduct of NIH-funded human subjects research must fulfill the education requirement. These individuals are considered to be “key personnel” and include Principal Investigator(s) on NIH awards that include research involving human subjects, all individuals responsible for the design or conduct of the study, and those individuals identified as key personnel of consortium participants or alternate performance sites if they are participating in research that involves human subjects.”

Indeed, the FAQ may have made it less clear by stating “Investigators who are identified as Key Personnel, but are not involved in the design and conduct of human subjects research do not need to comply with this requirement.” So it is not just those identified

as Key Personnel, but does include anyone involved in the design and conduct of the research. Contact with NIH personnel to clarify this indicates that the NIH believes, in essence, that *anyone who has contact with human subjects* during the course of a research project is considered key personnel for the purpose of this rule.

This indicates that even part-time temporary interviewers and supervisory staff must receive HSP training. While different institutions still have latitude to decide for themselves who is considered key personnel and who must be trained, and some do not define interviewers as such, many others are moving to ensure that interviewers are trained in HSP for all survey research projects (not just NIH-funded projects).

### WHAT TRAINING IS REQUIRED?

The NIH is also not specific on what constitutes sufficient training. The original notice states that "...all investigators need education in the basics of human subjects research." but the FAQ document states clearly "(T)he NIH does not endorse any specific educational programs. We believe that institutions are in the best position to determine what programs are appropriate for fulfilling the education requirement. Institutions may require a particular program or may choose to develop a program to meet the requirement." The FAQ does however point one to the NIH Bioethics Resources list (<http://bioethics.od.nih.gov/>). And the NIH does offer a free tutorial Protecting Human Research Participants that institutions "may elect to use to meet the human subjects protections education requirement."

While the training required for Principal Investigators is generally more rigorous, several institutions have developed other training resources for lower level personnel involved in the conduct of research. While *by no means comprehensive*, below is a list of what some institutions and survey research firms are doing to comply with the regulations:

- 1) Require staff to complete the NIH online training.
- 2) Require staff to read the textbook: *Protecting Study Volunteers In Research: A Manual for Investigative Sites* (3rd ed.), Dunn, C.M., & Chadwick, G.L. (2004), Boston: CenterWatch, Inc. This includes a test at the end of the book. One issue with this approach for survey researchers is that it is heavily geared toward clinical research.
- 3) Require staff to complete the Collaborative Institutional Training Initiative's (CITI) Social and Behavioral Research training module. This can be tailored to your institution's needs. Indeed several institutions require only a short version of the CITI Social and Behavioral Research training which includes only a few of the most relevant modules for interviewers. These often include: History & Ethical Principles, The Regulations and the Social/Behavioral Sciences, Assessing Risks, Informed Consent, and Privacy and Confidentiality. One issue with this approach is that joining CITI can be expensive unless your institution already subscribes.

- 4) Develop an in-house training and testing program. Some incorporate this in basic interviewer training and some have developed a specific HSP training course. Some require participants to pass a test and some do not. In addition, some require staff to sign a “Pledge of Confidentiality.” While these programs vary widely, in addition to some institution specific issues, most cover the same core contents that are relevant to front-line interviewing staff. These often closely align with the five CITI modules listed above.

## CONCLUSION

While institutions at this time still have wide latitude to determine who constitutes Key Personnel, many are opting to take the safe approach and see that *all* personnel that have contact with human subjects during the conduct of research. Clearly individual institutions and firms can decide what education is necessary to meet the NIH requirements, and as noted above there are many resources available to help achieve this.