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**University of Kansas School of Medicine**

**Department of Preventive Medicine and Public Health**

**Department of History and Philosophy of Medicine**

**RE: Compliance with NIH requirements for training in the responsible conduct of research**

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**Applicability**

The NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training grant, career development award (individual or institutional), research education grant, or dissertation research grant must receive instruction in responsible conduct of research. The NIH policy applies to Institutional research training grants, individual fellowship awards, career development awards (institutional and individual), research education grants, dissertation research grants, or other grant programs with a training component that requires instruction in responsible conduct of research as noted in the funding opportunity announcement. The policy applies to the following programs: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, TL1, TU2, and U2R and others as noted in the funding announcement.

**PRVM 853: Responsible Conduct of Research**

Students who have completed the University of Kansas School of Medicine course, “PRVM 853: Responsible Conduct of Research,” meet NIH requirements for this training. The following information can be used in grant applications.

The course, “PRVM 853: Responsible Conduct of Research,” educates graduate students, post-doctoral fellows, and researchers from a variety of scientific disciplines and clinical and laboratory workplaces in the responsible conduct of science. The course addresses major topic in research misconduct and research ethics; develops a toolkit for dealing with subject protections, integrity of the research process, and issues of data management, conflict of interest, and whistleblowing; and offers insights on ethical norms and consequences for violations. Issues of authorship, peer review, and mentoring are addressed. Participants learn relevant guidelines, policies, and codes relating to biomedical research and develop approaches to identifying and resolving ethical conflicts that arise in research.

The course is based on an active learning model through in-person class sessions and twelve weekly on-line case discussions in which participants analyze real and fictionalized situations for each of the areas identified in NIH texts and guidelines for instruction in responsible conduct of research.

To earn credit for the course, students must participate in the face-to-face class sessions and all on-line case discussions by reading assigned materials, considering viewpoints and arguments presented by the professor and classmates, and by contributing their own insights. In addition, each student serves as a discussion leader for at least one on-line weeklong case discussion. The discussion leader prepares an initial short summary of the case (including rationale for and against a chosen course of

action), posts questions for discussion, and submits an analytical summary of the discussion which is evaluated by the professor. This interactive approach is designed to foster learning in a dynamic environment with direct application of underlying theories and principles to real-world experiences of the participating students.

The full set of topics covered includes: research conduct, data management, animal subject protection, human subject protection, conflicts of interest, authorship, peer review, publication, collaboration, mentoring, whistle blowing, and genetics and privacy. Several cases are designed to raise integrative issues that cut across these specific topics, especially at the start and conclusion of the semester.

Students must also complete specific on-line training and testing modules for Health Insurance Portability and Accountability Act (HIPAA) and Human Subject Protection available through the University of Kansas School of Medicine.

### **NIH Reporting Requirements**

#### *For Institutional Training, Education, and Institutional Career Development Awards:*

Continuation (Type 5) applications must describe the nature of the instruction in responsible conduct of research and the extent of trainee and faculty participation as required in the PHS 2590. This report must include a description of any enhancements and/or modifications to the five instructional components from the plan described in the awarded application. Specific training faculty members who were contributors to formal instruction in responsible conduct of research during the last budget period must be named.

#### *For Individual Fellowships:*

Continuation (Type 5) applications must report specifically on instruction for the fellow in responsible conduct of research. This report must include subject matter covered, format, frequency and duration of instruction, or indicate when during a previous or future budget period instruction in responsible conduct of research did or will take place. The report should discuss both formal and/or informal instruction in responsible conduct of research and should note the extent to which the sponsor or senior fellow participated in these activities.

#### *For Individual Career Development Awards:*

Continuation (Type 5) applications must include a description of instruction in responsible conduct of research as required in the PHS 2590. This report should describe instruction, or participation as a course director, etc. in the case of senior career awardees, in both formal and informal instruction in responsible conduct of research in the past budget period, if applicable. If instruction, or participation as a course director, etc., occurred in a prior budget period, the PI should note the date of occurrence. Any activities undertaken to individualize instruction appropriate to the career stage of the PI should be discussed.

#### *For Dissertation Awards (R36):*

Continuation (Type 5) applications must report on instruction in responsible conduct of research under a separate heading. This section should describe participation in both formal and informal instruction in responsible conduct of research in the past budget period, where applicable. If

instruction occurred in a prior budget period, the PI should note the date when formal instruction was last completed. Any activities undertaken to individualize instruction appropriate to the career stage of the PI should be discussed. The report will describe how the mentor participated in these activities.

**Additional Resources (links active as of April 2014)**

NIH Notice NOT-OD-10-019

<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>

NIH Training in the Responsible Conduct of Research

<https://grants.nih.gov/training/responsibleconduct.htm>

NIH Office of Research Integrity

<http://ori.hhs.gov>