EXAMPLE #1 (K24):

WARNING: Please do not copy either section verbatim

[Introduction – insert introduction specific to your program]. The following outlines the RCR plan for this program:

- 1) Format: As a foundation for decision making in ethical situations, Washington University (WU) has created a series of eight online RCR education modules called the Program for the Ethical and Responsible Conduct of Science and Scholarship (PERCSS). The modules were developed by a panel of distinguished WU Researchers from a variety of disciplines to allow for an interdisciplinary approach to RCR education. All Scholars will be required to complete all eight modules of the PERCSS program within their first semester of participation in the program (approx. 2 hrs of instruction). In addition to the online curriculum, WU provides half-day Research Ethics Workshops twice a year co-sponsored by the Clinical Research Training Center (CRTC) and the Office of the Vice Chancellor for Research. These are face-to-face workshops on issues in Research Integrity and Compliance with a lecture format immediately followed by case studies facilitated by research faculty to discuss the identified topics outlined in the lecture portion (approx. 4 hours of instruction annually). Additional RCR education is available in a variety of formats in human subject's research, animal research and confidentiality of patient records (2-5 hours). The Program will also leverage regional RCR education opportunities. In particular, the Center for Clinical Research Ethics (CCRE) offers a series of five lectures annually on emerging ethical considerations. Finally, one-on-one mentoring on ethical conduct of research will occur throughout the program facilitated by faculty mentors.
- 2) <u>Subject Matter</u>: The PERCSS modules include the following eight subject areas: Introduction to Ethical and Responsible Research; Authorship and Publication; Collaborative Research; Conflict of Interest; Data Ownership, Acquisition, Sharing, and Management; Mentor-Trainee Relationships; Peer Review; Research Integrity. The face-to-face Workshops include elements of the above subject matter but also include elements of financial accountability, human and animal regulatory frameworks and ethical issues, research misconduct policies and situations, protecting the environment, and community impacts of research. All Scholars will be given four publications: the WU Research Integrity Policy, Conflict of Interest Policy, Judicial Code, and the pamphlet "On Being a Scientist", published by the National Academy of Science. They are expected to read these texts to prepare for the RCR training sessions. In Addition scholars will have the opportunity for one-on-one discussions of human subject issues and responsible conduct of science in the past, present, and future with the director of Institutional Review Board (IRB) in a town hall meeting setting. They will be required to attend a live review of the human subject application at an IRB meeting to gain an insider's view of what that entails.
- 3) <u>Faculty Participation:</u> Faculty members were directly involved with creation of the PERCSS program. The mentor and faculty from the training program will be actively engaged in RCR education for the

Scholars and will provide appropriate additional curriculum and discussion depending on the selected Scholars' particular areas of focus.

- 4) <u>Duration of Instruction</u>: PERCSS = 2 Hrs; Face-to-Face Workshops with lecture/case studies = 4 hours; Human and animal subject ethical education and/or laboratory safety education = 3-6 hours; ongoing faculty mentoring in ethical conduct of research as necessary.
- 5) <u>Frequency of Instruction</u>: Initial PERCSS completion will occur in the first semester after appointment of a Scholar to the Program. At least one face-to-face workshop should be attended within the first year of appointment. Additional formal education as deemed beneficial by the faculty mentor should be completed within the first two years of participation. Ongoing informal education will occur throughout the program and as appropriate for the career stage of the scholar and their area of interdisciplinary focus.
- 6) Reporting and Documentation: All formal online and workshop coursework will be monitored for Scholar attendance and completion within an electronic web-based platform called the Washington University "Compliance Profile", an electronic tracking mechanism for all formal RCR education requirements for documentation and reporting purposes. Faculty mentors will keep track of Informal RCR education sessions and will report on activities as required in the PHS 2590 and NIH policy. In addition, all scholars will sign a confidentiality agreement upon enrollment to reduce barriers to open communication around potentially sensitive issues that they may face, such as conflicts of interest, research integrity, scientific authorship, policies for handling misconduct, responsibilities of data management and dissemination of research results.

(Author: Office of Sponsored Research Services, Danforth Campus)

EXAMPLE #2 (KL2):

Responsible Conduct of Research Training: I have successfully completed the web-based Collaborative Institutional Training Initiative (CITI) Course in the Protection of Human Research Subjects, HIPAA training, and the two-day course Mentoring and Supervision for the Responsible Conduct of Research. I completed the course Ethical and Legal Issues in Clinical Research as a component of the core curriculum for the Masters of Science in Clinical Investigation. My education and training in responsible conduct of research will continue with the course Bio 5011 Ethics and Research Science. Topics discussed in the class include data management, data sharing, responsible authorship, conflict of interest, and policies for handling misconduct. I am a member of the BJH Ethics Committee and Co-Chair of the Organizational Ethics Subcommittee. I will meet monthly with *Dr. John Doe* to review topics in research ethics and attend educational programs sponsored by the BJH Ethics Committee and the WU Center for the Study of Ethics and Human Values.

(Author: Monique Williams, M.D., M.S.C.I)