

Template for NIH Instruction in the Responsible Conduct of Research

This section is limited to 1 page for individual award applications for Fellowships (F) and Career Development (K), and to 3 pages for Institutional Training (T) award applications.

Renewal applications must describe any changes in formal instruction over the past project period and plans for the future that address any weaknesses in the current RCR instruction. All training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application.

Please adapt this template to your particular circumstances. For more information, see Requirement for instruction in the [Responsible Conduct of Research](#), the [SF424 \(R&R\) Application Guide](#), and RCR information available at [CITI](#) and [BMS Course 6010](#).

Note: Please delete blue text and examples, leaving only the headings, before PDF conversion and uploading.

Introduction : Wayne State University (WSU), in compliance with the requirements of the National Institutes of Health (NIH) and the National Science Foundation (NSF), is committed to training relevant personnel in the Responsible Conduct of Research (RCR) who are funded by these agencies to conduct research. In response to the 2009 announcements of both the NIH and NFS requiring RCR instruction to be provided, WSU implemented RCR modules as part of their online Collaborative Institutional Training Initiative (CITI), which also provides IRB and IACUC training at WSU. Training in RCR is an ongoing process at WSU.

Format: Wayne State University provides a comprehensive RCR training plan which includes: 1) formal training via the online Collaborative Institutional Training Initiative (CITI); 2) formal coursework- BMS 6010, "Responsible Conduct in Biomedical Research"; and 3) ongoing informal, one-on-one training from faculty/mentors. The CITI training initiative is required for IRB approval at WSU and the additional online RCR modules fulfills part of the requirements relating to social and behavioral responsible conduct of research. The WSU School of Medicine supplementally requires the BMS 6010 course, which focuses on adherence to federal regulations and ethical requirements in conducting clinical and scientific research. This one-credit course is compulsory for all School of Medicine students and post-residency trainees.

Subject Matter: Topics covered in the CITI online modules and BMS 6010 coursework include, but are not limited to: conflict of interest – personal, professional, and financial; policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices; mentor/mentee responsibilities and relationships; collaborative research including collaborations with industry; peer review; data acquisition and laboratory tools; management, sharing and ownership; research misconduct and policies for handling misconduct; responsible authorship and publication; the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research.

Faculty Participation: All live lectures and small group discussions are taught by University faculty and staff with extensive experience in the subject matter. Instructors leading journal club sessions also stimulate informal discussions involving RCR topics. Additional RCR discussion also occurs throughout the applicant's training within the institution in the course of interaction with mentors and research meetings.

Duration of Instruction: The online CITI training modules are offered at the start of graduate studies at WSU and are refreshed on a yearly basis. All of the formal BMS 6010 coursework associated with RCR instruction are covered over the span of approximately one semester. Instruction consists of at least 18 hours, delivered as six weeks of live lectures and group discussions. Additional face-to-face RCR discussions with faculty and mentor(s) are on- going.

Frequency of Instruction: Trainees must participate in all RCR programs at their earliest opportunity. As previously mentioned, RCR is formally renewed through the online CITI training modules. Beyond successfully completing the coursework, interactive discussions regarding RCR occur throughout the program facilitated by the faculty mentor(s).

How Participation in RCR Instruction is Monitored: CITI training compliance is administered under the University's Office of the Vice President for Research, as is the responsibility for: administration of grants and contracts, management of intellectual property, oversight of human subject and laboratory animal research, and implementation of the university's policies on research. Additionally, the BMS 6010 RCR program is

monitored in several ways: signed and dated class attendance rosters, electronic transcripts, online class registration, and a final grade of Satisfactory ("S") or Unsatisfactory ("U"). Attendance is mandatory. In the event of an absence, participants are required to submit a 3-4 page analysis of a case report based on that day's topic of discussion. In addition to attendance, trainees are expected to be actively involved in all class discussions and activities. Because research is being done in a multitude of subject areas, having input from all trainees is essential to having a discussion that sees a situation from multiple viewpoints.