

Responsible Conduct of Research

(NIH Instructions: Every NRSA trainee must receive instruction in the responsible conduct of research, and each training grant application must include a description of the plan to provide trainees with formal and informal instruction on scientific integrity and ethical principles in research. Institutions are encouraged to incorporate this instruction into the training of other non-NRSA supported pre- and postdoctoral trainees. Review of applications lacking a plan for instruction in the responsible conduct of research may be delayed until a plan is provided. **Copy and Paste** the following text as the description for the **Instruction of Responsible Conduct of Research** at the School of Medicine☺

The Wayne State University School of Medicine requires all research students and post-residency students to take, for academic credit, a course in Responsible Conduct of Research. This course is part of the Graduate Program and covers such areas as integrity in science, scientific misconduct, applying for funds, plagiarism, mentoring, HIPAA, conflict of interest, data ownership, use of human subjects in biomedical experimentation, behavioral investigation committee, and the use of animals in biomedical experimentation. These topics are presented and explained to the students in a general sense often citing specific policies and regulations that have been developed by the School/University. This course is part of the Biomedical Sciences (BMS) program and is taught by Dr. Daniel Walz, Assistant Dean for Graduate Research and Education in the School of Medicine.

Course Catalog Description: BMS 6010, Responsible Conduct in Biomedical Research. Cr. 1, Offered for S and U grades only. Required of all School of Medicine students/post residency trainees. Undergraduate prerequisite: Written consent of (Insert name of department) Department chairperson. Nature, motivation and ethics in biomedical science situations liable to fraud, misconduct, conflicts of interest, and plagiarism in research, in peer and editorial review, and in authorship. Methods of safe laboratory practice and ethical human and animal use as research subjects in science.

WSU Responsible Conduct in Research On-line Training Programs were established in accordance to National Institutes of Health policy requirement for all investigators, submitting NIH applications for grants or proposals for contracts or prior to receiving a new or continuation award for research involving human subjects, to complete an education program on the protection of human research participants. The policy stated, "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." This policy was developed to indicate one way in which the Federal government through the Department of Health and Human Services (DHHS) intended to strengthen its commitment to the protection of human research participants by addressing the education and training of researchers.

In response to updated requirements from the National Science Foundation (NSF) and the National Institutes of Health (NIH), Wayne State University offers a basic course in the Responsible Conduct of Research (RCR) that can be applied toward these training requirements. This on-line course accessible via the University's Research Compliance website (<http://research.wayne.edu/compliance/>) employs a curriculum known as the Collaborative Institutional Training Initiative (CITI), which is also used for IRB and IACUC training at WSU. For the RCR requirements, additional discipline-specific training and/or face-to-face educational sessions may be required by the funding agency and/or the research program.

The Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org must be completed before HIC approval can be given to a research project. The Human Participants components consist of modules that focus on the protection of the human participants in research such as 1) the Basics of Research, 2) The History and Ethical Foundations of Biomedical Research, 3) Compliance with the WSU MPA, 4) The Continuum of Approval, 5) The Process of Informed Consent, 6) Roles and Responsibilities, 7) HIPAA, the Privacy Rule and You, and 8) Vulnerable Subjects-Prisoners, etc. The Vertebrate Animal components consists of various modules that focus on areas such as 1) History & Background of Ethics in Animal Subject Research, 2) Maintaining the Public Trust, 3) Federal Regulations and Regulatory and Accreditation Agencies, 4) Roles and Responsibilities of Players in the Research Process, 5) The Process of Using Animals in Research and 6) The Continuum of Approval. The Research Misconduct course covers modules focusing on areas such as 1) Maintaining the Integrity of the Research Record, 2) Bringing a Concern to the Attention of the University and 3) OVPR & the Assistant Vice President for Research. Upon completion of these training modules an individual certification of completion is issued.

Wayne State University is aware that these training requirements and regulations apply to *all agencies* of the federal government and require training for all key personnel and support staff in the following areas:

- a) Data acquisition, management, sharing, and ownership
- b) Mentor/trainee responsibilities
- c) Publication practices and responsible authorship
- d) Peer review
- e) Collaborative science
- f) Research involving human subjects
- g) Research involving animals
- h) Research misconduct
- i) Conflict of Interest and commitment
- j) Environmental Health and Safety

The Office of Environmental Health and Safety (OEHS), as a division of Research Support is committed to providing quality environmental health and safety management services for University students, faculty and staff. They are dedicated to educating the University community about occupational and environmental health and safety issues as well as providing professional services in the area of hazardous waste minimization and disposal, biosafety, food safety, pest control, indoor air quality, health and safety training and consultations. This office in collaboration with other University departments and safety oriented committees, strives to develop and implement effective health and safety programs that will ensure compliance with all local, state, and federal health regulations. Various laboratory health and safety training programs focusing on OSHA laboratory standards, Hazardous Waste/Emergency Procedures, Biosafety Training, and Radiation Safety Training are accessible through this website: <http://www.oehs.wayne.edu/>

WSU Policy and Procedures regarding Scientific Misconduct are available for download at: <http://www.research.wayne.edu/misconduct/index.php>.

(May want to include a statement which says at what point in the process the NRSA candidate/trainee will receive this training in the responsible conduct of research. May also want to include a statement on how during this orientation various issues such as student conduct, cheating, plagiarism, proprietary information, integrity of research data, appropriate authorship, conflict resolution, policies for handling misconduct and the handling of animals and human subjects in research are addressed.)