# INSTRUCTION IN RESPONSIBLE CONDUCT OF RESEARCH

Wake Forest School of Medicine (WFSM) considers education in the responsible conduct of research to be one of its major responsibilities to the research community. Courses and workshops are coordinated through the WFU Graduate School of Arts and Sciences and the Clinical and Translational Science Institute (CTSI). Each trainee in a federally sponsored training program is required to meet the eight contact hours of instruction in Responsible Conduct of Research as outlined in NOT-OD-10-019 and revised in NOT-OD-16-122. This includes discussion of relevant topics within required courses and journal clubs, and regular in-person discussions with their faculty advisors.

## A. RCR Training for Undergraduate Students

### Workshops Sponsored by the CTSI

CTSI staff (which includes the Office of Sponsored Programs, the IRB, and the IACUC) offer multiple educational workshops each month to the WFSM research community, most of which discuss ethical issues in the context of the specific topic (e.g. grant applications, manuscript publication, animal welfare, and human subjects research). These are listed at <https://ctsi.wakehealth.edu/education-and-training>. Recommended courses include:

*Introduction to the Responsible Conduct of Research (RCR)* –This 3-hour workshop provides an overview of the nine standards for the responsible conduct of research, which include: 1) Protection of Human Subjects, 2) Welfare of Laboratory Animals, 3) Research Misconduct, 4) Conflicts of Interest, 5) Mentor and Trainee Responsibilities, 6) Data Management Practices, 7) Collaborative Research, 8) Peer Review, and 9) Publication Practices and Responsible Authorship. Presenters are WFSM Office of Research staff. In addition to a basic introduction of the foundations, core principles, regulations, institutional systems and current issues concerning RCR, case examples will be presented which will reinforce issues presented and will provide attendees with an opportunity to participate in discussion. Objectives of the workshop are to: 1) gain a comprehensive knowledge of the basic principles of RCR; 2) raise awareness of the importance of; and 3) explore major ethical issues surrounding RCR and the nine standards. Participants will receive an RCR Basics Certificate indicating completion of the workshop. This workshop has been scheduled during the summer to facilitate all of WFSM R25 and T35 and medical student summer research program attendance.

*Responsible Conduct of Research (RCR): Sticky Situations in Publishing* –A panel of experts leads a 2- hour discussion of case studies covering commonly encountered – and tricky – situations related to RCR in manuscript preparation and publishing. Panelists will share their insights and experiences as mentors, administrators, co-investigators and co-authors. To address RCR training requirements for NSF, NIH, and other sponsors, it is strongly recommended that all postdoctoral fellows attend this workshop. Graduate students, research associates, and faculty at all levels are also encouraged to attend.

## B. RCR Training Required for Graduate Students

### GRAD 713, 714 Scientific Professionalism: Scientific Integrity (2 semesters, 1 credit each semester)

The students will use the Problem-Based Learning (PBL) method to identify discipline-specific and broad professional norms and obligations for the ethical practice of science. Content will include the norms and principles for the responsible conduct of science such as data acquisition, management, sharing and ownership, publication practices, and responsible authorship. Emphasis will be placed on learning the tenets of responsible conduct of research, the current regulatory and legal climate as well as the underlying norms and principles that shaped these concepts. Topics will include the student and advisor relationship, laboratory dynamics, collaborations in science, appropriate handling of data and appropriation of credit, plagiarism, conflicts of interest and financial responsibility. Students will acquire skills to recognize ethical issues in the practice of science, identify role obligations, and develop sound ethical reasoning to address these issues. Graduate students are required to attend GRAD 713 and 714; they are also encouraged to participate in the CTSI-sponsored RCR workshops and elective coursework (below) upon approval by their primary mentors.

**Duration of instruction:** The first year course includes 9 contact hours of lecture and 17 contact hours of small group sessions.

## C. RCR Training for Early Career Scientists

### Research Integrity Training for Early career scientists (RITE)

Research Integrity Training for Early career scientists (RITE) offers a new Responsible Conduct of Research Training in a format tailored to early career scientists at Wake Forest School of Medicine. A designated RCR Coordinator (David Lyons, PhD, Director IACUC & Animal Welfare Program and Deputy Research Integrity Officer, Clinical and Translational Science Institute at the Wake Forest School of Medicine) provides program oversight.

RITE meets and exceeds the NIH requirements for Responsible Conduct of Research training for post-doctoral fellows (F or T awards) and early career faculty (K awards). This series consists of facilitated conversations between early career scientists and senior faculty/staff about how to succeed in academic science today with an emphasis on the central importance of research integrity.

The curriculum is developed by a steering committee of at least four faculty members with active research programs. It is designed to address components of the nine instructional cores of RCR (Publication Practices and Responsible Authorship; Research Misconduct; Peer Review; Conflict of Interest; Research Involving Human Subjects; Research Involving Animals; Data Acquisition, Management, Sharing and Ownership; Collaborative Science; Mentor/Trainee Responsibilities).

The RITE series consists of at least four training sessions per academic year (**Table 1**). Each two-hour face-to-face session is led by Wake Forest School of Medicine faculty and invited speakers, offering eight contact hours annually. A typical session will consist of a short 15-30 minute review of fundamental concepts, (e.g., “What is good data management”), a short 15-30 minute review of current practices at Wake Forest (e.g., “What are Wake Forest-specific expectations for data security and the specific tools at Wake Forest to achieve them”), followed by one hour of open discussion using case-study material as needed.

#### Table 1. RITE Series (Format: two-hour, face-to-face formal discussion)

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| **Date** | **Topic** | **Presenters** |
| 09/25/2019 | Best Practices in Research Collaboration & Global Discovery: Responsibility, Disclosure, and Data Security | Joseph Andrews, PhD, Research Integrity Officer; Assistant Dean for Regulatory AffairsDavid Lyons, PhD, Deputy Research Integrity Officer, Responsible Conduct of Research Training CoordinatorDr. Dawen Zhao, MD, PhD, Associate Professor, Biomedical Engineering |
| 11/12/2019 | Entrepreneurship in an Academic Setting: Lessons from the Lab | Todd Lowther, PhD, Professor, Department, of Biochemistry, Center for Structural BiologyDeepika Poranki, PhD, Senior Innovations Associate, Wake Forest Innovations |
| 04/01/2020 | Best Practices for the Oversight of Recordkeeping: Shared Electronic Lab Notebooks and more | TBD |

## D. Additional Training Required for Staff, Trainees, or Faculty who Conduct Human Subjects Research

Per federal regulations, WFSM is responsible for assuring that “all activities related to human subjects, regardless of funding source, will be guided by the ethical principles in the Belmont Report.” Thus, WFSM requires completion of the Collaborative Institutional Training Initiative (CITI) online training in human subjects protections for all individuals engaged in research involving human subjects. Ethical issues (e.g. confidentiality, vulnerable subjects) are discussed in each module, as well as a revised Common Rule course that covers the regulatory updates to the Common Rule (45 CFR 46, Subpart A). The course includes graded post-tests requiring a minimum score to receive a completion certificate. Training must be renewed via a refresher course every 3 years. The Institutional Review Board (IRB) requires proof of CITI training for the study team before protocol approval.

## E. Additional Training Required for Staff, Trainees, or Faculty who Conduct Animal Subjects Research

WFSM offers certification in animal subjects research online via the American Association for Laboratory Animal Science (AALAS) learning library, which can be accessed at <https://ctsi.wakehealth.edu/animal-laboratory-training>.The library consists of online modules that can be accessed by computer inside or outside the institutional firewall. Modules were designed to provide required information on the humane care and use of laboratory animals as mandated by federal regulations.

The Institutional Animal Care and Use Committee (IACUC) monitors completion of training modules; protocols are not approved unless all research personnel have completed the appropriate modules. The Principal Investigator for the project must ensure that an individual is in the eIACUC system before that person can access the training modules. All new research personnel involved with the use of animals in research must complete the 4 base modules of the AALAS learning library.

The eIACUC system will then determine which additional modules or courses may be required, based on the individual’s role on the project. Subsequent modules are species-specific and are required as needed for the protocol in which the individual is involved. Multiple training sessions are available for specific procedures and species of laboratory animals, and are announced on the website and in regular CTSI announcements to the WFSM community.

## F. Elective Coursework in the WFU Graduate School of Arts and Sciences

*Ethics and Responsibility in Clinical and Population Translational Science* (THSS 704)

*Biomedical Research Ethics* (BIE 702)

*Clinical Ethics* (BIE 705)

*Ethics of Health Communication* (BIE 709)

## G. Additional RCR Educational Resources

### Online Library of RCR Case Studies

The current RCR curriculum for biomedical graduate students at the WFU Medical Center Campus is fully automated via a curriculum-management system called eWake, developed and managed in-house by the Office of Academic Computing. Course and background reference materials are available to facilitators and students; cases can be presented directly to small groups via the web, and grading is completed online.

### Other Events

Trainees will be encouraged to attend the seminar series and other events sponsored by the Wake Forest Center for Bioethics, Health and Society. Examples include a panel discussion called “What Can We Learn From Charlie Gard?” (November 30, 2017), and a lecture by Dr. Paul Lombardo (Regents’ Professor & Bobby Lee Cook Professor of Law, Georgia State University) called “The History of Eugenics in the United States” (February 26, 2018).

### Compliance

While the NIH does not require certification of compliance or submission of documentation, as stated on NOT-OD-10-019, it does expect institutional monitoring and documentation of instruction in responsible conduct of research by individuals supported by any NIH training/research education/fellowship/career award. WFUHS /WFU [respective institutional administrative section] maintains a record of all its NIH-supported trainees, fellows, and scholars have received the required instruction. Records include course attendance documentation (e.g. attendance rosters) and certificates of course completion; records are kept for at least 5 years from completion date.