CCRE
CENTER FOR CLINICAL & RESEARCH ETHICS

ICTS 2018-2019 Responsible Conduct of Research (RCR) Course
Course Syllabus

COURSE BACKGROUND
Eligibility
This course is sponsored by the Institute for Clinical and Translational Science (ICTS) at Washington University in St. Louis. The course is offered at no charge to trainees and scholars who are members of the Washington University Institute for Clinical and Translational Sciences (ICTS) and are enrolled in the 8-hour course. (Individuals needing fewer than 8 hours of RCR instruction are encouraged to contact the Office of the Vice Chancellor of Research to find a suitable RCR program that can meet their training needs). Students, faculty, and scholars at Washington University may join the ICTS at no cost online: Join the ICTS here.

Registration
To track completion of course requirements, scholars must register for (a) the course (register here) and (b) each individual session using links provided in the CCRE RCR Course Calendar. Scholars must also sign in at individual sessions. Completion of the course requires 8 hours of attendance (see Course Requirements below for details). To manage class size, participation for each session is capped at 50. Priority for seats in an individual session will go to those registered for the session. If a scholar is registered for the course but has not registered for a session, he or she will be permitted to sign in and attend the session only as space permits.

Prerequisite
Course participants are expected to complete the online PERCSS Core Curriculum prior to attending the first face-to-face session. The PERCSS curriculum requires approximately 2 hours to complete: Complete PERCSS online here. Completion of the PERCSS Core Curriculum is documented in your WUSTL Research Gateway Compliance Requirements profile and will be verified by the RCR Course Program Coordinator.

The prerequisite serves several purposes:
- It provides baseline knowledge required to participate meaningfully in the ICTS RCR Course
- Whereas participants in the ICTS RCR Course have some flexibility to select topics according to their interests, the PERCSS program ensures exposure to seven core areas of RCR instruction: authorship and publication; collaborative research; conflict of interest; data ownership, acquisition, sharing, and management; mentor-trainee relationships; peer review; and research integrity.
- The PERCSS modules link to relevant WUSTL policies and resources, which will assist scholars in complying with the expectations of all research faculty and trainees at WUSTL.

COURSE MASTERS AND CONTACT INFORMATION
Alison Antes, PhD, Assistant Professor of Medicine, Division of General Medical Sciences, Assistant Director, Center for Clinical and Research Ethics, ICTS RCR Course Co-Director

Jessica Mozersky, PhD, MBE, Division of General Medical Sciences, Assistant Director, Center for Clinical and Research Ethics, ICTS RCR Course Co-Director

Instructors: Please see the [CCRE RCR Course Calendar](#) to identify the instructors for individual sessions. Most instructors are WUSTL faculty with active research programs and mentoring experience. Many are affiliated with the ICTS [Center for Clinical and Research Ethics (CCRE)](#).

For questions regarding the syllabus or sessions, please contact, Cyndi McKenna, the Program Coordinator at ccre@wustl.edu.

COURSE DESCRIPTION AND OBJECTIVES

The ICTS RCR Course consists of a 2-hour foundations session, which presents professional decision-making strategies and applies them to research scenarios,[1] and a series of 1-hour face-to-face seminars on diverse topics pertaining to the responsible conduct of research (RCR). All seminars that fulfill course requirements will address one or more of the following RCR topics: conflicts of interest; human subjects protections; animal welfare; mentor/mentee responsibilities and relationships; collaborative research; peer review; data acquisition, management, sharing and ownership; research misconduct; responsible authorship and publication; the scientist as a responsible member of society; contemporary ethical issues in biomedical research; or the environmental and societal impacts of scientific research. **We encourage scholars to select sessions in dialogue with their research mentors to ensure that a variety of topics are addressed and that individual needs are met**.

Course Format: The sessions encourage active participation through methods such as small and large group discussion, case scenario analysis, and brief brainstorming activities. Scholars are expected to participate actively in all course sessions. The sessions also frequently draw upon SMART Strategies for Professional Decision-Making.™ These strategies were originally developed for the Professionalism and Integrity in Research Program (PI Program) and are appended to the syllabus.

The **objectives** of the program are to foster:
- Sensitivity to ethical issues, institutional policies, and regulatory requirements in research
- Good professional decision-making skills in research
- Awareness of resources at WUSTL and elsewhere that support the responsible conduct of research

COURSE REQUIREMENTS

Scholars must attend and complete evaluations for a minimum of 1 Foundations session (2 hours) and 6 additional 1-hour sessions to complete the course for a total of 8 hours of face to face instruction. Each session on a particular topic will only count once towards completion of the course, so scholars should ensure that they attend 6 *different* sessions in addition to the foundations session. Scholars are welcome and encouraged to attend additional sessions beyond the required 8-hours.

Late Arrival and Early Departure Policy. Course participants must plan to arrive prior to the start time of each session to sign in to document their attendance. Participants will not be permitted to join a session late.

Leaving prior to the conclusion of a session will result in loss of credit for the session.

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[1] The Foundations session is the only specific session that must be completed; all other sessions are "selectives." We encourage, but do not require, scholars to attend the Foundations session first or early in the progression of sessions.

This policy ensures the integrity and accuracy of our documentation of participation in the RCR course, as trainees participate in these sessions to fulfill NIH training requirements. The course completion certificate verifies 8 full hours of instruction. In order to ensure that the curricular goals approved by NIH are met within our ICTS RCR program, we only recognize events listed on our RCR course calendar toward completion of the course (http://ethicsresearchcore.org/education/rcr/rcr-course-calendar).

Documentation of Course Completion. Once the Program Coordinator verifies satisfaction of attendance requirements, scholars will be emailed a certificate of completion.

 COURSE CALENDAR
All course sessions are listed on the CCRE RCR Course Calendar.

Ordinarily, at least one session will be offered each month, and sessions will be posted at least 3 months in advance to allow scholars to plan their schedules accordingly.

EVALUATION
We ask scholars to complete evaluations of individual sessions.

COMPLIANCE WITH NIH AND NSF INSTRUCTION REQUIREMENTS
The RCR course is designed to satisfy the NIH Requirement for Instruction in the Responsible Conduct of Research. It may also be incorporated into plans to satisfy NSF RCR training requirements.

Scholars are expected to complete an RCR instruction program at each stage of their training (e.g., corresponding to pre-doctoral, post-doctoral, or career development awards). Scholars are encouraged to select specific sessions in discussion with their mentors to ensure that instruction best meets their needs. Mentors who are interested in participating as RCR program faculty should contact ccre@wustl.edu.

LINKS TO RCR RESOURCES

WUSTL Center for Clinical and Research Ethics
http://ethicsresearchcore.org/

National Ethics Center
https://www.nationalethicscenter.org/

The US Office of Research Integrity
https://ori.hhs.gov/

NIH Office of the Director, RCR Resources
https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training

National Postdoctoral Association, RCR for Postdocs
http://www.nationalpostdoc.org/?RCR_toolkit

Strategies for Professional Decision Making: The SMART Approach[2]

Professionalism & Integrity IN RESEARCH

Strategy	Dimensions	Sample Reflection Questions
Seek Help	**Seeking information** **Requesting mediation** **Welcoming correction**	**Where might I seek additional information or an unbiased, objective opinion?** **Would it help to involve a mediator or consultant?** **Do I welcome correction or input from others, including subordinates?** **Have I owned up to mistakes and apologized as necessary to move forward with all involved?**
Manage your Emotions	**Identifying emotions** **Managing emotions** **Both positive (excitement) and negative (depression, anxiety, anger) emotions**	**What are my emotional reactions to this situation? Am I anxious, frustrated, or depressed? Feeling pressure or urgency?** **How might my emotions influence my decision-making?** **Would taking a "time out" or deep breath help? Using "Freeze Frame" technique?** **Am I managing stress each day?**
Anticipate Consequences	**Consequences to others and to self** **Long-term and short-term consequences** **Positive and negative consequences** **Risk management**	**What are the likely short-term and long-term outcomes of various choices?** **Who will be affected by my decisions and how?** **How might this decision impact my career and me?** **Which outcomes in this situation are controllable? Which cannot be changed?** **How can risks be minimized?** **How can benefits be maximized?**
Recognize Rules and Context	**Recognize rules—formal (e.g., laws & policies) and informal (prevailing social norms)** **Recognize the power dynamics (e.g., social hierarchies, decision-makers)**	**What are the causes of the problems in this situation? Which causes can I change?** **What ethical principles, laws, or regulations apply in this situation?** **What factors place limitations on my choices?** **Who are the decision-makers in this situation?** **Does anyone have the power to control outcomes? If so, who and how?**
Test your Assumptions and Motives	**Test your assumptions and unspoken rules** **Examine your motives** **Empathically compare your assumptions and motives to those of others**	**Might I be making faulty assumptions about the causes of the situation, alternatives, or other's intentions? How can I find out?** **What are my motives? Are they the same or different as those I serve?** **Could self-serving biases be distorting my perception of the situation?** **How will others view my choices?**
Notes:	**The strategies are related and overlapping, but they have distinct elements. E.g., testing assumptions is sometimes a good way to manage emotions and it can lead to seeking help.**	

Want to be SMARTER? Add "Evaluate" outcomes of your actions, and "Revise" your approach based on outcomes.