NEW NSF AND NIH RESPONSIBLE CONDUCT OF RESEARCH (RCR) GUIDELINES: A THREE-PHASE PLAN*

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For many university compliance officers, the introduction of new guidelines on the Responsible Conduct of Research (RCR) from the NIH and the NSF was another in a series of new regulatory boxes to check off on the compliance score card. Already juggling HIPAA, FDA, IACUC, IRB and COI, the federal mandates for RCR education and training represent another unfunded and time-consuming mandate that must be implemented throughout the organization. To that end, we have set out to create a cost-effective and efficient approach to delivering quality research ethics education that not only meets the federal standards, but, more significantly, integrates bona fide ethics education and responsible conduct across our entire research community. In what follows, we discuss the challenges that any research ethics program will encounter—planning and organization, faculty engagement and development, program assessment, and institutional sustainability—and describe the three-tier approach we developed.

In January 2010, new requirements for Responsible Conduct of Research instruction were announced by the National Science Foundation (NSF).6 The University of Miami has, for nearly two decades, conducted a vigorous RCR program. This program, coordinated by the University of Miami Office of Research and the UM Ethics Programs, was designed to meet the requirements of the Public Health Service (PHS), as specified by the National Institutes of Health (NIH).7 This PHS/NIH-mandated program essentially complies with and in many respects is more rigorous than the new NSF requirements. In addition, at our institution, RCR education is also required by particular schools and departments for their affiliates who may be involved in research, regardless of their funding source(s). Presently, RCR education consists
of online training via the Collaborative Institutional Training Initiative (CITI Program) and/or various face-to-face “live classroom” options.

In addressing the new requirements, it was decided that our goal in the expansion of the existing RCR program should not be one of mere compliance with the new education mandate. Instead, we aimed to make the University an exemplar in research ethics education. Immediately, our RCR program and its implementation plan had to be expanded to include the new NSF-mandated population of scientists and engineers:

“[E]ach institution that applies for financial assistance from the Foundation for science and engineering research or education [must] describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project.”

This means both expanding the cohorts of students to be addressed, as well as broadening the case studies and topic areas of emphasis.

In addition, we updated our plan for RCR education and divided it into three phases. RCR-1, now in place, offers RCR instruction to all persons reached by the PHS and NSF mandates. RCR-2 will offer the same RCR instruction, on an optional basis, to all graduate students and post-docs who are not already covered by RCR-1. RCR-2’s expansion is designed to accommodate students and post-docs whose schools and departments mandate RCR instruction regardless of funding source, and those who wish to have such instruction even if it is not required of them. RCR-3, designed in anticipation of a future institutional mandate, will make RCR instruction required for all UM graduate and post-doctoral fellows, with the exception of students in professional schools (e.g., business, law, and medicine) that participate in other professional conduct training and are allowed to opt-out.

**RCR-1**

RCR-1 adapts and expands upon decades of experience with RCR requirements at institutions conducting PHS-supported research and includes two parts: (1) a face-to-face (“seat time”) course, called Research Ethics and (2) individual online training using the CITI Program’s RCR Curriculum.
Research Ethics Course

Students and trainees on PHS- and NSF-supported projects are required to participate in a formal course, “Research Ethics,” which adopts a curriculum largely shaped by PHS guidelines but which also features discipline-appropriate cases and resources. The curriculum addresses the nine long-established topics of RCR, below, as well as new ones that are increasingly common as part of the RCR corpus:

1. conflicts of interest and commitment - personal, professional, and financial
2. policies regarding human and animal subjects (if appropriate to the audience); and safe laboratory practices for such subjects
3. mentor/mentee relationships and responsibilities
4. collaborative science and research, including collaborations with industry
5. peer review
6. data acquisition, management, sharing and ownership
7. research misconduct and policies for managing misconduct
8. responsible publication practices and authorship responsibilities
9. the scientist as a responsible member of society, contemporary ethical issues in scientific research, and the environmental and societal effects of scientific research
10. intellectual property issues (patent, copyright, trademark)
11. whistle-blowing and dispute resolution
12. export controls, national security and “dual-use” technologies
13. current events in the discipline (a.k.a., “hot topics”)

The face-to-face course is taught by teams of two or more faculty members, at least one of whom has a background in research ethics; when possible other member(s) of the teaching team, recruited from the school’s or department’s faculty, provide(s) additional disciplinary background specific to the audience. Course sessions consist of approximately 6-8 classroom contact hours, typically split into two 3-4 hour sessions. Sessions emphasize agreed-upon learning objectives related to each of the topics above, as well as discussion of domain-appropriate cases that reinforce those learning objectives. For example, students and trainees in psychology or cell biology are given the
opportunity to discuss cases involving psychology or cell biology; engineers explore cases featuring engineering issues; computer scientists focus on computing cases, etc. We plan to incorporate Audience Response System (ARS) devices to help promote engagement in class, to assess understanding of case materials in real time, and to confirm attendance by matching against sign-in sheets.

On-line RCR Training

In addition to classroom time, RCR education includes essential self-tutoring via online RCR training materials available at the CITI Program. CITI Program modules address most of the topics listed above, using discipline-appropriate content (text, cases, trigger videos) and references. Students are required to present a CITI certificate of completion to document fulfillment of their RCR requirements prior to admission to the face to face session. Other online resources will be made available via the University’s course management system, particularly for topics that are comparatively new such as whistleblowing, electronic health records, export control, and so forth.

RCR-2 AND RCR-3

Phases two and three are aspirational and part of a long-range plan to expand RCR education and special events to all students and faculty not currently subject to the PHS/NSF mandates. All activities itemized in the current phase (RCR 1) will be made available (RCR 2) and then required (RCR 3) for grad student and postdoctoral researchers, even if they do not receive PHS or NSF funding. In addition, undergraduates who are actively involved in research would also be included in the phase 3. It is our contention that RCR education ought to be a part of all scientists’ training, independent of their funding status. Thus, the goal of this expansion is to ensure that all scientists—and all future scientists—enjoy the opportunity to learn about and debate issues related to scientific integrity.

Faculty Engagement and Development

The NIH in particular has stressed that broad faculty involvement will be considered in evaluating the quality of an RCR program (see Appendix A). NIH has also increased the minimum contact time recommendation to eight hours. In order to meet the expanded demand for instructors, phases 2 and 3 will require a faculty development
component. Current ethics and science faculty involved in RCR will help colleagues to develop skills needed to communicate credibly to students about ethical issues in scientific inquiry. Those who wish to become RCR instructors or mentors will: (a) complete the online CITI RCR course, (b) teach at least one session (two class meetings) under the supervision of an experienced RCR instructor, and (c) commit to teaching at least two more sessions as part of a two-person teaching team during an 18-month period. To assist less experienced instructors, a basic RCR Handbook will be created; it will include learning objectives and case studies for each RCR topic and could be supplemented and customized by each instructor. We will use the course management system to facilitate collaboration and as an online teaching resource.

Responsible conduct of research instruction ought not be isolated in a series of experiences at the beginning of graduate school. We anticipate testing various configurations for delivering RCR content and developing follow-up opportunities. We will encourage faculty to develop and lead topic-specific conferences, seminars and lectures to complement formal RCR instruction. These sessions could address issues arising from specific research projects, current controversies or historical events that shed light on contemporary issues. Such sessions would be intended as informal opportunities for all students, trainees and faculty to address ethical issues raised by research. For example, electrical engineers might request a lecture on ethical issues raised by radio frequency identification and surveillance; physicists might seek a seminar or debate on the tension between data sharing and the goal of discovery priority; or computer scientists could ask for a panel to address challenges related to intellectual property.

**Evaluation of RCR Classes and Online Instruction**

All RCR phases will be subject to standard learning effectiveness and student “satisfaction” evaluation methodologies, including:

- Comprehension assessments in the classroom, via Audience Response System results. These results will be aggregated rather than tracked by student, unless it appears that individually identified data is necessary.
- Comprehension assessments for on-line content via multiple-choice quizzes required for completion of each CITI RCR module (lesson). These results will be tracked, and a minimum “passing” score will be required.
• Student surveys for in-class sessions, offered via the course management system or other on-line survey system.

• Surveys regarding CITI materials, offered as part of completion of the CITI RCR modules. Each CITI course offers a survey upon completion of an associated quiz. In addition to standard questions regarding course navigation and merit, questions related to how much students value RCR instruction, and how well the course materials prepare the students for further discussions of the RCR with peers, mentors and research supervisors will be included. Other questions will be included to assess the past experiences of student (e.g., mentoring, authorship) and whether the RCR course just completed has altered the students thinking or attitudes about the issues.

• Peer review of teaching quality (offered via RCR teaching “coaches”), reviews of course assessments, and optional formal evaluations by teaching specialists from the UM School of Medicine Educational Development Office or the UM Instructional Advancement Center.

Institutional Commitment

RCR-1, having expanded from PHS-only to PHS/NSF cohorts, has generated a substantial increase in annual RCR student cohorts at our institution. Annual cohorts will expand further for RCR-2 (covering students supported by any kind of funder) and even more for RCR-3 (all graduate students), increasing the instructional burden several-fold. Institutions establishing high-quality RCR programs—programs that demonstrate a willingness to transcend mere compliance—will need to identify adequate resources as their own cohorts grow. In order to develop a competent cadre of RCR instructors, particularly those with discipline-specific knowledge, there must be a formal commitment to faculty development. Given new NIH requirements of broad faculty involvement and increased minimum contact time, together with the expanded number of students any credible plan anticipates, it is clear that the nation’s research institutions have a rare opportunity to make commitments to ethics education that are as transformational as their commitments to science itself.
CONCLUSION

We recognize that institutional culture and economics have an impact on program development and implementation. We are fortunate to have at our institution a long history of support for ethics education and research as the basis for our proposals to expand RCR to all students and faculty, not just those identified in regulations. As with any instructional undertaking, to be successful we will have to demonstrate value, synergy and learner satisfaction.

NOTES

*A version of this article was presented by Dr. McCafferty at the 20th Annual Association for Practical and Professional Ethics Meeting, March 2011. It is based on and includes verbatim material from the internal memorandum Plan for Instruction in the Responsible Conduct of Research: Response to NIH and NSF Mandates September 2010 jointly prepared by the UM RCR planning group.

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5 Director, Special Ethics Initiatives, University of Miami Ethics Programs
8 See http://edocket.access.gpo.gov/2009/E9-19930.htm. Also: “Effective January 4, 2010, NSF will require that, at the time of proposal submission to NSF, a proposing institution’s Authorized Organizational Representative certify that the institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research.”

9 http://www.citiprogram.org. CITI’s has discipline-oriented RCR curricula oriented to engineering and mathematics, the physical sciences, and social sciences and humanities, among others.

10 The senior members of the UM RCR teaching team have used an iterative method to reach agreement on learning objectives for each of the RCR topics, similar to that described in DuBois, James M. and Dueker, Jeffery M, “Teaching and Assessing the Responsible Conduct of Research: A Delphi Consensus Panel Report” Journal of Research Administration (Vol. XL, No. 1 2009). A common set of presentation slides is used to structure the presentation of classroom topics. Online materials are also available on the UM Ethics Programs web site and the Blackboard course management system section created for RCR.
APPENDIX A

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<th>PHS/NIH</th>
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<td>&quot;[A]ll trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant. All &quot;new and renewal applications submitted on or after January 25, 2010, and for all continuation (Type 5) applications with deadlines on or after January 1, 2013. This Notice applies to the following programs: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K03, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K39/R00, K11, K12, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, T1L, T2U, and U2R. This policy also applies to any other NIH-funded programs supporting research training, career development, or research education that require instruction in responsible conduct of research as stated in the relevant funding opportunity announcements.&quot;</td>
<td>&quot;[T]hose students (undergraduates and graduates) and postdoctoral researchers who receive NSF funds (support from salary and/or stipends to conduct research on NSF grants).&quot; Requirement flows &quot;down to all subawardees, at any tier.&quot; The requirement does not apply to &quot;students who receive only scholarship or stipend support to enroll in an academic program through such NSF programs as S-STEM and Noyce.&quot; However, &quot;students must take RCR training if they receive NSF scholarship or stipend support to engage in research, or if conducting research is included in their academic program.&quot;</td>
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<p>| Content | &quot;While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction: 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 relationship; 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.&quot; &quot;While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all of the above topics.&quot; | Institution-determined |</p>
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<td>&quot;Substantial face-to-face discussions among the participating trainees/fellows/scholars/participants; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research are highly encouraged.&quot;</td>
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<td>While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction.&quot;</td>
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<td>&quot;A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs ... or unusual and well-justified circumstances.&quot;</td>
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<td>&quot;Instruction should involve substantive contact hours between the trainees/fellows/scholars/participants and the participating faculty. Acceptable programs generally involve at least eight contact hours.&quot;</td>
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<td>&quot;A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.&quot;</td>
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<td>&quot;Reflection on responsible conduct of research should recur throughout a scientist’s career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs and individual fellows/scholars are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years.&quot;</td>
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### Timing

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“It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Individuals at the early career investigator level (including mentored K awardees and K12 scholars) must receive instruction in responsible conduct of research at least once during this career stage. Senior fellows and career award recipients (including F33, K02, K05, and K24 awardees) may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the trainee, fellow or career award recipient is not actually supported by an NIH grant.”

### Faculty participation

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“Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research.”

“Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.”

Sources: