Beyond Responsible Conduct: Taking Responsibility for the Responsible Conduct of Others

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A unique Responsible Conduct of Research (RCR) course was created for Ph.D., M.D., and M.D./Ph.D. post-doctoral fellows and junior faculty at Northwestern University, some of whom had prior RCR training and some of whom did not. The unique feature of the course is its dual focus on learning the core elements of RCR and preparing participants for being responsible for guiding and monitoring RCR behaviors of others. These more advanced but still junior scientists are at a key junction where they are beginning to mentor and supervise others. A second unique element is a required conversation on at least two RCR topics with their current mentors, with a short written report, modeling explicit conversations about RCR prospectively. Overall response has been very positive with a high level of engagement. Formal and informal evaluation feedback reveals how participants see the value of the course and how it has shaped how they intend to guide others in the future. An important goal of the course is to also position high quality RCR and RCR training within the research environment, not just the classroom.

INTRODUCTION

From the inception of the NIH requirement for training in responsible conduct of research (RCR), the emphasis has been on providing research trainees with clear guidance on the expectations of the research community for the highest ethical, moral, and responsible research practices. In teaching young scientists how they should conduct research, the unspoken assumption has been that they will continue those practices as they become leaders of their own research. But there really has never been any systematic recognition and focus on what happens once they start hiring and mentoring others more junior than themselves. Furthermore, the expanding effort to enhance RCR training actually sends the message that one learns responsible practices not within but outside of the day-to-day research world, and that it is not the responsibility of those leading research teams to teach the core principles. In reality, the limited number of hours devoted to formal RCR training pales in comparison with the learning that takes place while doing research; the informal teaching and learning process of mentor-based training occurs non-stop. The NIH requirement that research mentors be involved with RCR training buffers this separation between formal and informal ‘classrooms’ but, again, only for a very limited period of time. Thus, very little formal or informal attention is given to helping young scientists envision how they themselves will apply and teach high standards of RCR to junior scientists for whom they become responsible.

FROM KNOWING WHAT IS EXPECTED TO GUIDING OTHERS

This importance of training young scientists to guide others becomes especially critical for those who are at the advanced postdoctoral and early faculty career stages. Beginning Ph.D. students are just trying to figure out the rules of the road for themselves, but postdocs and faculty are taking on responsibility for mentoring and supervising others. It is this population that we began focusing on in late 2009 at Northwestern University as a need arose to provide RCR training to postdoctoral (including clinical) fellows and junior faculty funded through NIH institutional and individual training mechanisms, particularly T, F, and K awards.

Two of us (RM and DMS) had been leading RCR training for various populations for many years and participated in various training workshops to improve the quality of our courses. One of us (RM) had even conducted formal research on RCR training through the ORI Research on Research Integrity funding mechanism. Despite having the perspective that comes with experience, developing an RCR course for this group of more advanced scientists and clinicians posed particular challenges. First and most significant, many of the postdocs and junior faculty had already taken at
least one and sometimes multiple RCR courses during their research training, but others (especially medical doctors) would be experiencing formal training for the first time. So our task was to create a course that would be valuable for the first timers without being another round of same-old, same-old for those who had heard it before. This led us to the idea that, as young researchers at the threshold of careers where they would have responsibility for training others, this cohort would benefit from RCR training that got them thinking about how they would cultivate a culture of RCR once they themselves are in charge of the lab or training environment. The emphasis would be less on how they as individuals should conduct research responsibly and more on the question of how to guide others to do so. Thus, we titled our new course: “Taking Responsibility for Responsible Conduct of Research.”

Our course meets once a week for ten weeks, 90 minutes per class. The topic areas overlap largely with those recommended by NIH (with some exceptions described below), and the teaching approach combines typical presentations and case study discussion. Individual classes are led by us (i.e., the course organizers) or by guest instructors with particular expertise in the day’s topic. We pay particular attention to areas where expected behaviors are not clear-cut or mutually agreed-to by the research community and different researchers would openly disagree (the ‘gray areas’). In this way, we consciously set up debate, and often discomfort, as a teaching tool to bring the often conflicting, invisible practices and philosophies out into the open rather than give the impression of uniform agreement. The importance of this approach came out of our previous qualitative research with Ph.D. students and postdocs in an RCR course. We found that it was quite easy to teach a new principle and get agreement when it did not conflict with either a person’s internal beliefs or the practices they had observed already. However, if an individual fundamentally did not agree with the precept or had seen it violated in the past, their thinking was unlikely to change unless these conflicts were brought out (I). Bringing these conflicts out also provides the new opportunity to shift the conversations to, “Ok, so what will you do when you are in charge and how are you going to teach others how they should behave?” This change in focus to being in charge and being responsible for others often created a palpable shift to a higher level of engagement and discussion than we had seen in the past.

A perfect example is authorship. Always, when we ask a group what level and type of contribution should be required for inclusion as an author, the initial primary focus is on anyone who had contributed with their own hands to the actual research that led to data included in the paper. As we walk through various editor and journal guidelines and point out the much higher bar for many, sympathy for including the undergraduate student—who only followed a protocol but ‘needs’ the publication—diminishes for some while others hold onto it. As the debate continues, we then shift the conversation to how they will make the decisions in the future, but most importantly, how they will explicitly convey their principles rather than leaving them unspoken. Invariably, a high fraction leave the sessions strongly committed to clear and open authorship guidelines to be discussed with new research team members. Most also leave with a strong commitment to having open authorship discussion as early in the research process as possible, knowing things can change as the work progresses.

**DIVERSITY OF PRIOR RCR TRAINING AND RESEARCH TYPES**

Another challenge for us has been the diversity of trainees taking our course. While the majority of trainees needing to meet the new NIH RCR requirements were in the medical school environment, a significant minority were twelve miles away on the Northwestern University main campus, working in the physical and behavioral sciences and in engineering. In order to eliminate the travel that would inconvenience some if we held class on a single campus, we adopted the model of videolinking class between locations on each campus. One of the course leaders was at each location to facilitate small- and large-group local discussion, and didactic presentation material could originate from either location. Early attempts to involve both locations in a single videolinked discussion were not particularly successful, but whenever possible, the two local groups convened via videolink following local discussion and reported out to the larger group.

A common question facing organizers of RCR training is how homogeneous the training groups should be. Certainly, there are benefits when trainees have (or can expect to have) relatively shared research experiences and practices and norms are more easily agreed upon. On the other hand, we find the extensive, multidimensional diversity of the trainees in our class to be extremely valuable. The mixture of Ph.D.’s and M.D.’s and the full range of research from basic to clinical to social/behavioral provides great breadth of perspective and dialogue. In fact, this diversity is quite useful for establishing initial discomfort around a topic that, as discussed earlier, can be so effective as a teaching tool.

**EVOLUTION OF TOPICS AND INCLUSION OF MENTORS**

Since its inception in 2009, we have continually made adjustments in content and format in an effort to improve the course. The NIH-recommended topics continue to form the backbone of the training, but we have augmented some of the topics in response to interest. For example, the topic of conflict of interest grew, and a second session form the backbone of the training, but we have augmented some of the topics in response to interest. For example, the topic of conflict of interest grew, and a second session session was added incorporating issues surrounding collaboration with industry, technology transfer, and challenges associated with balancing academic obligations with those associated with, say, contract work, or starting a company. This session is jointly led by a representative from the university’s tech transfer office and one or two faculty members who have successful commercial ventures as well as successful...
academic subjects research has expanded to include a session on the ethical issues associated with conducting human subjects research, especially clinical trials, in the developing world.

NIH guidelines stress the need to involve mentors—not just the trainees—in RCR training. This is commonly accomplished by recruiting mentors to serve as course organizers, lecturers, or discussion facilitators. We felt, however, that this approach tends to perpetuate the perception that RCR is learned in a classroom. To break from this view, we instead added as an assignment the requirement that each participant schedule a formal time with their mentor to discuss at least two of the topics covered in the RCR course. Afterward, the trainee submits a one- to two-page reflection on the conversation, highlighting how their mentor’s beliefs compare to what was presented in class, and describing any insights that emerged from the meeting. This assignment is typically first received with considerable eye rolling, but while there is variability, many of the reflections describe a quite positive and productive interaction that often lasts a lot longer than planned. Overall, feedback on this assignment has been favorable, with several trainees indicating it triggered conversations that should have taken place sooner or at the beginning of the mentoring relationship. In the several years since the inception of this assignment, we have never had a mentor resist or react negatively.

EVALUATION INFORMING UNDERSTANDING OF IMPACT AND IMPROVEMENT

Throughout the development of this course, we have conducted fairly extensive evaluation and feedback surveys. These have helped us refine and improve the course, but also allowed us to gauge the practical impact of the different topics covered, that is, whether the course changed the way a participant thought about a particular topic and whether or not the treatment of the topic was useful. The overall reactions to the course were consistently positive, with most seeing it as very helpful, not just meeting a requirement, and being more valuable than previous courses they had taken. After one course, we asked the question: “Overall, how and/or in what ways was the course effective in helping you to develop mentoring skills?” A high fraction of the respondents provided very explicit and positive ways in which it had, especially with regard to the RCR topics. One particularly clear response included: “Further, because of the course, when I serve as a mentor in the future, I will engage in more planned oversight of activities in my lab and will discuss RCR-related issues with trainees up front in a proactive fashion rather than only as issues emerge.” We also probed how participants and their mentors reacted to the required trainee/mentor conversation/reflection assignment. Surveys revealed little resistance by mentors with a general positive attitude to the conversations before they were conducted. Interestingly, responses revealed that many mentors’ view of the conversations became even more positive after having them, suggesting they could lead to more explicit discussions in the future. Across two courses, 59% and 78% of participants agreed or strongly agreed with the statement: “I could see the value of such conversations and would have them when I am mentoring others.” Finally, in one recent survey, we asked: “Would you recommend the series to a postdoc if s/he were NOT REQUIRED to take it?” Only 6% said No, with 64% choosing “Yes in most cases” or “Yes, with caution re: the time required.” To have such a high percentage feel it was worth taking even if not required was very gratifying.

ONLINE MODULES TO INCREASE DISCUSSION TIME

Since so many of the trainees in our course have already had RCR training at an earlier stage of their research career, it seemed like poor use of class time to cover basic, foundational material that many participants had covered before. We also found that even for those new to RCR, too much class time was being devoted to lectures delivering content at the expense of discussions of cases and real-life situations. As such, over the past year, we have begun creating web-accessible learning modules narrated by course instructors for topics requiring a great deal of foundational material. So far, learning modules have been created for research misconduct, conflict of interest, research with animals, and research with human subjects and materials. Modules deliver core content that learners review at their own pace in advance of class, but typically require about 45 minutes and have built-in assessments as a way to track learning. By delivering core content this way, class time can be spent in more interesting ways—e.g., discussing more case studies, sharing personal experiences, and having participants reflect on how they will insure that their own trainees adopt proper RCR practices and behaviors. We considered and reviewed on-line, publicly available modules, but eventually decided to create our own as this provided a close link to the faculty and leaders of each in-person class. The individuals who present the online modules are those who then lead in-class discussions going beyond the basics. This provides continuity and identification for them as key resources to be accessed as needed in the future. An unexpected benefit of this format change has been that it allows participants to communicate with the course instructors before the class in order to ask questions, provide examples from their own experience, and ask for advice on how to handle a particular situation. These pre-class interactions have proven quite valuable as they allow us to gauge “where students are” on a particular topic and to tailor classroom activities accordingly. The amount of pre-class communication has been unexpectedly high, possibly because of the relative privacy of the communications. We suspect that some individuals are not entirely comfortable discussing sensitive matters publicly—that is, in front of others they may work with or who know their mentor. Overall response to the pre-class modules has been very positive. They also will serve as resources for teaching RCR in other venues.
CONCLUSION

When we began this new approach to RCR, we did not know how people would react to it, especially those who had been through multiple RCR trainings before. The positive response, particularly to its usefulness, supported our impression that researchers at this career stage are ripe for assistance. They are confronting the realization that, as they move into positions of leadership in the scientific community, they must not only conduct and model responsible research, but assume responsibility for inculcating the next generation of researchers with the values consistent with the practice of responsible research. Raising not only RCR issues but also approaches to effectively dealing with them can turn an RCR course into a valuable professional development opportunity. The NIH 2009 RCR policy established the training requirement only for a small subset of federally funded postdoctoral researchers and junior faculty who meet the strict NIH definition of “trainee.” Our experience suggests that such training would be valuable for all research scientists and clinicians at this key career transition stage. Certainly for many institutions, ours included, the benefits of expanding RCR training beyond the current, relatively small, mandated population is balanced against the substantial logistical complications that would accompany any significant expansion. The challenges are numerous, not the least of which is identifying enough qualified personnel to lead the training. The nebulous status of postdoctoral researchers (not students, but not quite employees) at many institutions, and their often only tenuous connection to formal training programs (in contrast to the situation for graduate students) compounds the challenge. However, the costs of not expanding RCR training could, in the end, be much higher.

ACKNOWLEDGMENTS

The program described was supported by the National Center for Research Resources, Grant 5UL1RR025741, and is now at the National Center for Advancing Translational Sciences, Grant 8UL1TR000150. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. The authors declare that there are no conflicts of interest.

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