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# Assessing Student Learning in the Responsible Conduct of Research

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# Providing Professional Training in Research Ethics[1]

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## Introduction

Providing education in research ethics to faculty members and research support staff (hereafter referred to collectively as "professionals") can be challenging and thankless, especially when ethics or RCR[2] training is required by some distant power such as the Federal government. Some faculty researchers resent both the imposition on their time and the implication that they are not already ethical. Seasoned researchers can reasonably feel that they know all they need to know about the ethics of their own life's work.

It is arguable, however, that training in research ethics for professionals is of vital importance. A faculty researcher clearly has a greater potential to do damage than a mere graduate student, whether through his or her own misdeeds or failure adequately to teach research ethics to his or her own students.

Senior researchers often have a great deal of influence over their younger peers, subordinates, and students; they receive more Federal funding for their research; their publications are more widely read; in important ways, they set the standards. In other ways, however, the standards shift beneath their feet, and it is as important for them to keep up-to-date on changes in ethical standards as advancements in their research field.

This paper is intended to be of use to those who are handed the task of training professionals at their own institution in the responsible conduct of research. This paper is no substitute for experience, and certainly not for training in adult education. I myself have no formal training in adult education; I have learned by doing. If shortcomings are apparent in what I offer below to those with greater expertise, I will be grateful for suggestions for improving this paper.

I focus on the people with whom I have the most contact and of whom I have the best understanding – academic researchers and research administrators. I assume and hope that the comments here can be adapted to other research environments without too much difficulty.

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[2] RCR (responsible conduct of research), rather than research ethics, is the term preferred by the U.S. Federal government, including the National Institutes of Health and the National Science Foundation.

## Background considerations

My observation is that professional RCR training is typically provided by a junior researcher, an ethicist (usually from the philosophy department), or a research administrator (from, e.g., the IRB[3], the IACUC[4], the sponsored research office, etc.). Assuming that your RCR training is mandated from above, you can expect to reach a few enthusiastic individuals and to confront a larger number of resistant ones. If it isn't mandated, you will only get the enthusiasts[5], which will make your task easier.

For best results, **get support from above**. This is easiest to do right away; when the Vice President for Research (VPR) or the functional equivalent asks you to take on this task, indicate that you will need certain resources and moral support. The resources will almost certainly include the wherewithal to advertise your event (money for printing and mailing, perhaps), possibly room rental, possibly staff and technical support for a registration procedure, ideally refreshments (coffee, at least), and the like. Moral support should include, at a minimum, the VPR's signature on an invitation to attend the event; having the VPR give a short introduction at the event can also be helpful.

If you cannot get support from above, it will be much more difficult to get your work done and to reach the reticent. Still, you can reach the enthusiasts, which might be a step toward getting more support from above. You may be able to take advantage of existing institutional events – for example, most colleges and universities have at least one ongoing lecture series that is constantly in the market for substance.

Participants in your event should walk away feeling that it was **well worthwhile**. They won't feel that way if you just hand out regulations and bibliographies. Your event should be intellectually challenging as well as useful and practical. A certificate of completion often goes down well, even if it is only worth the paper it's printed on. You may think of other incentives or rewards appropriate to your situation.

Remember to have **reasonable expectations**; only a portion of your targeted audience will show up for your first event (even if it is mandated) – don't expect 100%. Also don't expect to cover all of the issues in one event. Be satisfied with a slow start, but be committed to building on it over time.

## Key questions

As you plan your event – which might be a 2-hour workshop, a semester-long series of weekly brown bag discussions, a lecture by a visiting scholar followed by discussion, or the like – you should consider a few key questions:

- **What problem do you want to solve?** What situation do you want to address? What do you want to accomplish?

[3] IRB = "Institutional Review Board," responsible for overseeing research with human subjects. This is the most common term in the United States; "Human Subjects Committee" is also common, and outside of the U.S., "Research Ethics Committee" is common.

[4] IACUC = "Institutional Animal Care and Use Committee," responsible for overseeing research using non-human animals.

[5] By "enthusiast," I only mean someone who does not have to be convinced that this is an important issue.

- **What do you know about the state of play?** Is the problem widespread? How long has it been going on? What classes or groups of people are involved (faculty, graduate students, staff, etc.)? Does your knowledge arise from anecdote or something more rigorous – do you have any statistics or records to back you up?
- **What resources (time, money, etc.) can you allocate?** Where will your resources come from? Whose time? What incentives can you offer for participation? What disincentives for non-participation can you offer? With whom can you brainstorm? Who can help in other ways?
- **How long can you wait for real success?** What external and internal forces do you need to placate?
- **How will you know success when you see it?** What will count as success? Where will you get your data? How will you decide what next steps, if any, you should take?

I'll illustrate with two examples.

## Example A

Your university has a Federal mandate requiring all research and research staff working on projects that receive NIH funding to receive training in the protection of human subjects of research.[6]

The first step is to read the mandate carefully and develop an interpretation. It might be wise to find out how other institutions interpret it and what they plan to do to meet it. If your university has ongoing relationships with peer institutions, capitalize on them. (For example, Indiana University belongs to the Committee on Institutional Cooperation, or CIC[7], - the Big Ten universities plus the University of Chicago.) You may choose to meet the mandate to the letter or to go beyond it for better results.

In consultation with the VPR, you decide to create a Web-based tutorial supplemented by a Web-based certification quiz (20 multiple-choice questions) and a tracking system. This seems doable given the resources and time available.

As you gather your team, some questions arise. Is there any way to find out quickly how many researchers and research staff already have some kind of training in the protection of human subjects, what they already know about the topic, what their attitudes are about the topic – do they think it's important, or just an obstacle? If you have such information, or can get it readily, take it into account as you design your training. Most likely this information is not readily available and you do not have the time or resources to generate it.

Because of the mandate, you have ten months to put the training in place. Given the gravity of failing to comply, the VPR has persuaded a few researchers to help and directed several research administrators to cooperate with you. You also have a small budget, and the IRB and sponsored research office have agreed that, once the system is in place, they will not work with any researcher until he or she is certified.

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[6] This example is based on the NIH policy on "Required Education in the Protection of Human Research Participants" issued in 2000. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Accessed 25 Feb 2008.

[7] See http://www.cic.net/index.shtml. Accessed 25 Feb 2008.

In this case, merely meeting the mandate counts as success, and you can wait only as long as the mandate allows to succeed. You may not consider a hurriedly constructed program to be **real** success, however, and you may opt to improve and build on it at your leisure.

### Example B

Some of the staff and members of the IRB, including yourself, are dissatisfied with the quality of protocols submitted by many faculty and graduate students. You note that two professional schools seem to be in the worst shape. You also have a sense, based on rumor and anecdote, that too many researchers are performing human subjects research without IRB approval. "Too many" is undefined.[8]

You resolve to address these problems through education and increased visibility. You want to have the first event by the next semester, or the one following at latest, and continue hosting events for two years. The IRB staff and some members will work on this, along with a few researchers who will be invited to make presentations. No one will receive additional pay for helping out. You ask the VPR for a small budget for meeting space, advertising, and refreshments at meetings; your request is granted.

You start by getting in touch with the Office for Human Research Protection (OHRP) to explore collaborating on a Research Community Forum.[9] Organizing the forum will take at least 6 months, so you plan smaller-scale lead-in events.

The IRB chair starts attending faculty meetings, especially in the schools that seem to need the most help. The goal is to give the IRB a human face, to outline the IRB process, to listen to their concerns, and to remind them of the possible gravity of non-compliance. The chair does her/his best to make clear that the IRB's goal is to facilitate, not obstruct, research. "If you think it's hard to work with us, trying working with the Federal government directly."

You organize two two-hour workshops for each of the next two semesters; 3 of the 4 are held in the schools of most concern and focus on issues of interest to them. One member of the IRB and two researchers make presentations at each workshop and plenty of time is allocated for discussion.

The IRB staff, chair, and a few members offer to visit classes and other previously-scheduled events to talk about the IRB process. The offer is accepted by a few researchers.

The Research Community Forum is eventually held with excellent attendance.

As the two-year effort winds to a close, the IRB staff has a sense that things have improved, but no hard evidence.

## Conclusion

In my experience, the most difficult and unsatisfactory aspects of educational interventions in the responsible conduct of research for faculty and staff are (1) drawing them in and (2) evaluating your success. Problem (1) doesn't hurt as much if you remember to have

[8] This example draws on a number of actual events at IU combined with features of events from other universities and my imagination.

[9] OHRP is a Federal agency in the National Institutes of Health. See http://www.hhs.gov/ohrp/education/#activities. Accessed 25 Feb 2008.

reasonable expectations; you won't always fill the room and you probably won't ever get every one of member of your target audience involved, and a small gathering is better than none (usually).

Problem (2) is linked, to some extent, to (1) – low attendance can be seen to correlate to low success, high attendance to high success. More important is the impact, and, as may be clear from my discussion above, without real data on the situation before and after the educational event, impact is very hard to assess. Most often, it seems, we must make do with event evaluation (an expression of satisfaction by attendees might be the best we can get) and a general sense of the atmosphere. Considering that a general sense of things, rather than hard data, often drives these initiatives, perhaps those measures are adequate.

I am also convinced that the most important key to success is to offer many opportunities. Low attendance at one event might be the result of the weather or any of a host of other unpredictable factors. The more high-quality events you host, the more word will spread that they are worth attending. Indeed, I believe that the mere fact of holding such educational events improves the climate of research at a university.