

# Educational Approaches to the Responsible Conduct of Clinical Research: An Exploratory Study

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## Abstract

### Purpose

To identify best practices in education related to the responsible conduct of clinical research (RCCR).

### Method

American Society for Bioethics and Humanities (ASBH) members involved with teaching RCCR were asked to complete an online survey, followed by an in-depth telephone interview. The online survey asked about respondents' RCCR teaching, trainees, and institutional context. The phone interview involved discussions about teaching strategies, institutional context, and needs. The study was conducted between 2003 and 2005.

### Results

Forty-eight respondents to the online

survey indicated a breadth of topics being covered in RCCR curricula; 35 respondents indicated that their RCCR teaching applied toward institutional RCCR requirements. Among the 21 instructors interviewed, many described a wide variety of teaching responsibilities. Recommended teaching strategies included fostering interactive discussion, using skills-based exercises such as designing IRB applications, accommodating students' individual interests in curriculum design, involving experienced researchers, involving trainees early in their careers as well as requiring continuing education, and designing a curriculum with a clear view of educational objectives. Interviewees described the institutional supports they needed, and they noted that insufficient

support sometimes undermines RCCR teaching goals. Participants generally agreed that RCCR education should be required.

### Conclusions

Strong agreement among participants concerning recommended strategies for teaching RCCR provides useful, if provisional, guidance to instructors and institutions charged with providing such training. The study suggests a need for substantial investments in RCCR training, studying outcomes, and developing mechanisms to ensure the quality of instruction.

Acad Med. 2007; 82:32–39.

**E**thical issues in clinical research and in reporting the results of this research have recently captured public attention. A number of initiatives have emerged to ensure that clinical research is conducted in a manner that comports with established ethical standards and is otherwise sensitive to ethical considerations—including the recently released Association of American Medical Colleges' (AAMC's) publication, "Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials."<sup>1</sup> Our study focuses on practices and perceptions on the part of faculty engaged in responsible conduct of clinical research (RCCR) education.

The United States federal government has stimulated institutional initiatives for

training in responsible research conduct. Institutions that receive National Institutes of Health (NIH) funding for specific research training programs are required to include responsible conduct of research education for trainees. The NIH encourages programs to consider instruction in five general areas: conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, and data management.<sup>2</sup> However, the policy does not establish a specific curriculum or formal requirements with respect to any of these topic areas.<sup>2</sup> An attempt at the federal level to implement a training mandate in the responsible conduct of research with a broader reach and with more specificity has failed.<sup>3</sup>

With respect to clinical research in particular, the NIH requires that all researchers involved in the design and conduct of NIH funded human participants research complete training in the ethical aspects of human participants research.<sup>4,5</sup> Again, specific educational

programs and teaching methods are not specified by the NIH policy.

Commentators have advocated for an expansion of the federal mandates or have called on institutions to take the initiative to develop training programs and require participation for all researchers and staff involved in research, not just projects funded by the NIH.<sup>6–8</sup> The federal government has supported research and course development relating to research integrity, for example, through the Department of Health and Human Services' Office of Research Integrity's RCR Resource Development Program.<sup>9</sup> Efforts also have been made to develop model core curricula to be applied across disciplines or within a particular discipline.<sup>10–12</sup> However, few studies have examined the content and effectiveness of institutionally based RCCR training, and no broadly accepted approach has emerged.

Furthermore, there is considerable controversy both within the biomedical

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research community and within the organizations that fund and regulate biomedical research about a number of topics, including conflicts of interest, intellectual property, research on vulnerable populations, and research in emergency settings. Over the last few years, controversies in these areas have made international news. Often, these controversies highlight fundamental ethical conflicts that could be addressed by RCCR training courses.

To identify best practices in RCCR education, we surveyed and interviewed members of the American Society for Bioethics and Humanities (ASBH) about their methods of teaching, because these members are likely to be responsible for educational efforts in RCCR.

## Method

This project was supported under a cooperative agreement from the Office of Research Integrity (ORI) through the Association of American Medical Colleges (grant number US2MPORI01). Although the award was made to ASBH, the contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of the AAMC, the ORI, or the ASBH.

A working group of ASBH members with recognized expertise in RCCR was assembled to conduct this study. The study was conducted from 2003 to 2005. It included two phases: an online survey and a phone interview, both conducted at the University of Minnesota. The working group drafted the questions for both phases of the project, pilot tested the questions with ASBH board members, and revised them according to the input received. Instruments for both phases of the study are available on request. The study was deemed exempt by IRBs at the institutions affiliated with working group members.

To identify potential participants, a former president of ASBH (JL) sent a message via electronic mail to all ASBH members (approximately 1,300). The message invited members who teach RCCR to participate in the study by completing an online survey. The online survey asked participants a series of questions about their RCCR teaching and the context in which they were teaching. It used yes/no and multiple-choice

questions to inquire about participants' roles in RCCR education (e.g., primary instructor or guest lecturer), the types of institution within which they work, the types of learners they teach, the topics they cover, the teaching methods they use, whether their curriculum satisfies an institutional requirement, and whether their approach to teaching has been affected by professional involvement in addressing allegations of misconduct at their institutions. Participants were automatically assigned numbers to preserve their confidentiality. At the end of the survey, participants who indicated that they were willing to engage in the phone interview phase provided identifying information so that they could be contacted concerning an interview. Identifying information was kept separate from the online survey data. ASBH members who were not involved in teaching RCCR were asked not to complete the survey.

Of all online respondents, six individuals indicated, at the end of their online survey, that they were not willing to participate in the interview phase of the project. We invited the remaining respondents to participate in the phone interview phase of the study. The phone interview followed a standard format. It asked open-ended questions about participants' involvement in teaching RCCR, their learners, the changes they had made in their teaching over time, their views about the effectiveness of their teaching and about the most effective ways to teach RCCR, the institutional supports and barriers they had encountered in their work, their involvement in dealing with allegations of misconduct and how it may have shaped their teaching, and what advice they would offer to others who might be developing RCCR curricula. All interviews were recorded and transcribed, and any information that might identify an individual or associated institution was removed from the transcripts before analysis.

Two of the researchers (DD and SS) independently reviewed the transcripts, noting emergent themes. They subsequently met to discuss and compare their observations, and they reached agreement on codes. This draft analysis was presented to the entire working group, and consensus was achieved on the analysis of the data.

## Results

We received 51 completed surveys but analyzed only 48. Two surveys were omitted because they had inconsistent responses from the same person. Another person, who also responded twice, had identical responses for every question; therefore, one of these sets of responses was deleted from the data set. There is no systematic information about who teaches RCCR, either nationally or within the ASBH membership. Thus, it is not possible to calculate a true response rate for this survey. Most of the respondents who provided identifying information were from different institutions. However, five institutions (to protect confidentiality, named here A, B, C, D, and E) were represented by more than one respondent to our online survey. Three people from institution A responded, and two from each of B, C, D, and E. Some of these individuals worked in different departments within their institution or on different campuses.

Of the 42 respondents whom we invited to participate in the phone interview phase of the study, 21 accepted our invitation. Only two of these individuals were from the same institution.

### Online survey

Tables 1 and 2 summarize the results from the online survey. The majority of respondents (31/48, 65%) stated that they were serving more than one role as an RCCR instructor, such as being a primary instructor as well as a periodic guest lecturer (see Table 1). Sixteen percent were teaching RCCR at two or more types of institutions, for instance, a private and a public academic institution. They were teaching a broad variety of types of learners, and they tended to teach a number of different types of learners (as opposed to teaching only graduate students, for example, or only principal investigators).

As shown in the Table 2, the RCCR instructors reported that they cover a breadth of topics in their courses. They reported generally using interactive teaching strategies, with 41 of 48 respondents indicating the use of discussion at least some of the time. Other strategies beyond lectures included simulations, case studies, observations in the field, role plays, and mock town hall discussions.

Table 1

**Summary of Data from Online Survey of 48 Instructors in the Responsible Conduct of Clinical Research (RCCR), 2004**

Characteristics	No. (%) respondents
<b>Type of institution*</b>	
Private academic institution	22 (46)
Public academic institution	22 (46)
Nonacademic institution, hospitals, pharmaceutical companies, government agencies	13 (27)
<b>Institutional requirement for RCCR</b>	
Applies toward requirement	35 (73)
Does not apply toward requirement	13 (27)
<b>Instructor role*</b>	
Primary instructors	25 (52)
Part of team-taught course	30 (63)
Periodic guest lecture	27 (56)
Other: course coordinators or directors, creators of online curricula or video presentations, and discussion leaders	10 (21)
<b>Trainees*</b>	
Graduate students	41 (85)
Principal investigators	32 (67)
Faculty	28 (58)
Other study personnel	24 (50)
IRB members	23 (48)
Other: advocates, pharmacy personnel, industry medical personnel, protocol development personnel, industry legal departments, clinicians; fellows (research, postdoctoral, international), residents, medical students/physicians in training, undergraduates	17 (35)
<b>Teaching methods*</b>	
In-person discussions	41 (85)
In-person lectures	41 (85)
Online modules	17 (35)
Other: written materials (texts and articles), case study analysis (case studies provided in written and/or video format), a field requirement to observe an IRB, simulated patient instructors, role playing in groups, mock IRB meetings, mock town hall discussions, research papers	10 (21)
<b>Involved with dealing with allegations of scientific misconduct</b>	
Have been involved	12 (25)
If involved, felt experience changed approach to teaching	9 (75)
Have not been involved	36 (75)

\* For these items, the participants were allowed to choose "all that apply" in the survey question.

Most respondents (35/48, 73%) stated that their teaching helped students meet an institutional requirement. We found no statistically significant association between the type of institution (e.g., public or private academic institution) and whether the RCCR instruction would count toward an institutional requirement. The survey did not ask instructors to specify whether the requirement at their institution was driven by federal mandates.

Notably, 75% of respondents with experience dealing with allegations of scientific misconduct reported that this experience had changed their approach to teaching RCCR. This finding suggests that such experience motivates instructors to design their curricula to more directly address the topic of scientific misconduct. Indeed, our telephone interviews indicated that instructors with such experience tend to do so, for example, by incorporating

discussion of actual cases of misconduct or FDA warning letters into their teaching.

**Telephone interview**

A number of themes emerged in the interviews. As we discuss below, participants evidenced a strong commitment to their work, described a demanding workload, recommended key teaching strategies, suggested useful materials, and enumerated their instructional needs.

**Attitude toward RCCR teaching.**

Participants tended to communicate a very strong commitment to their work and emphasize the importance of their RCCR teaching. One instructor exclaimed, "I feel like a missionary" (#21).

**Demanding workload.** Many participants described a wide variety of teaching responsibilities. Some taught full courses in RCCR. However, most gave guest lectures or taught short workshops or parts of larger courses (e.g., on research methods, or clinical ethics more generally). Participants often reported that their workload encompassed not only teaching responsibilities—including both curriculum design and actual teaching of RCCR as well as other courses—but also service responsibilities. Many of them serve on IRBs, for example, or on clinical ethics committees. A number of them stated that they must work to garner institutional support for and understanding of RCCR training needs. One interviewee remarked:

It's just such labor-intensive work to get buy-in from other departments, to [get them to] see that they need a whole course, and not just part of a course, to convince them that they can't do it themselves on a three-hour little web thing [that would be] as good as the full-fledged thing is. . . . So it's labor intensive, making the pitch. (#38)

**Recommended teaching strategies**

Participants recommended a number of teaching strategies, which we describe below.

**Fostering interactivity.** Every interviewee stressed the importance of fostering discussions whenever possible by using case studies or other interactive discussion methods. Participants acknowledged that this sort of teaching might be more resource intensive than

Table 2

**Topics Included in Responsible Conduct of Clinical Research (RCCR) Curricula by 48 Instructors Participating in an Online Survey, 2005**

Topics	No. (%) respondents
Ethical requirements for informed consent (e.g., process of obtaining consent, writing consent documents, conducting consent sessions)	43 (90)
Ethical principles and research	41 (85)
Analyzing risks and benefits of research	38 (79)
Confidentiality and privacy (e.g., HIPAA)	37 (77)
Conflicts of interest	37 (77)
Vulnerable populations	35 (73)
IRB approval process	34 (71)
History of human subjects research	32 (67)
Therapeutic misconception	31 (65)
Recruitment (e.g., paying subjects, recruitment fees for researchers, acceptable recruitment strategies)	31 (65)
Research design (e.g., placebos, randomization)	30 (63)
Authorship	24 (50)
Data management (e.g., fabrication and falsification, data objectivity, data safety monitoring)	24 (50)
Federal requirement for the inclusion of women, minorities, and children	23 (48)
Topical issues (e.g., genetic research, stem cell research, fetal tissue research, biotechnology)	23 (48)
Science and society	21 (44)
International research	19 (40)
Publication of negative findings	19 (40)
Community-based research	17 (35)
Whistle blowing and reporting misconduct	17 (35)
Public health research	16 (33)
Intellectual property	11 (23)
Grants management	3 (6)
Other:	15 (31)
• Mentoring	
• Peer review	
• Collaborative science	
• Justice issues regarding costs borne by participants, including responsibility for costs associated with research related injuries	
• Decision-making capacity	
• Mental health/psychiatric research	
• Cultural competence/special populations	

other instructional strategies such as lectures and would thus require greater institutional investment than less desirable strategies. Instructors mentioned various ways to create a dynamic classroom environment. Instructors may introduce cases that they have designed themselves or gleaned from other sources (e.g., texts, journal articles), or they may ask students to provide case studies from their own experience, which then could be used by instructors or students to facilitate discussions. Alternatively, instructors might assign students positions on a case study and require them to construct a justification for that position. Or,

instructors could design activities involving role playing (e.g., researcher, IRB member, research participant, etc.). In general, respondents recommended keeping class sizes small enough to foster discussion, or presenting short lectures to larger groups, followed by small-group breakout sessions for discussions.

Interactivity is also possible online. When instructors described their experiences teaching online, either as a completely online course or as a supplement to a face-to-face course, they mentioned online discussion boards and live chats as important teaching strategies. Many instructors questioned the wisdom of

having a large number of enrollees in face-to-face classes; similarly, online instructors seemed particularly passionate about keeping class sizes manageable, given the time-intensive nature of online teaching. The case discussions, personal examples, and role-playing exercises described by teachers in face-to-face contexts seemed to translate well into an online environment. Nevertheless, one seasoned online instructor suggested that, in an ideal world, the course would be blended, with at least some face-to-face meetings solely devoted to case discussions (#43).

**Promoting practical application.**

Another trend was the emphasis on applying ethical principles through practical, skills-based exercises and explorations. In the words of one interviewee,

See one, do one, teach one, is what they say over in the medical school for how you learn something. . . . Sure you can see a lecture or get exposed to a lecture. [You need to find] some better way to translate the theoretical and the didactic into . . . practice, so it's not a theoretical thing. (#43)

Examples of more applied, hands-on strategies included creating an IRB application, evaluating real or mock proposals to IRBs, attending IRB sessions at the institution and evaluating the process, and designing a consent form.

**Accommodating students' interests.**

Many instructors stressed the need to include materials, assignments, and class activities that would encourage students to address issues relevant to their particular fields and to explore their own interests. The following comment is typical:

I think the main thing is to develop materials and approaches that seem relevant to the trainees in terms of the work they do and can stimulate them to be reflective about how ethics relate to either what they're doing or what they're learning how to do. . . . Trying to bring it home is really important. (#6)

Participants acknowledged that instructors can "bring it home" without completely redesigning their approach to teaching for each new group of students. As one participant explained:

The cases themselves evolve. . . . I don't think the structure changes much. . . . The particulars change, but the

fundamental, ethical analysis strategies don't. (#23)

One helpful, yet simple, strategy mentioned was having students themselves generate discussion questions and cases. Instructors would tailor their presentations and discussions accordingly. Similarly, instructors have developed specific strategies to meet the needs of diverse groups of students. For example, one instructor's training audience includes both pediatric researchers and researchers who never work with children. Instead of devoting one week to issues involving only children and losing the attention of researchers who do not work with children, this instructor instead

incorporated the pediatric cases throughout the six-week course. That way there seemed to be always something to engage the pediatricians and no week where the rest of the group said "Well, you know, I can kind of mentally check out." (#9)

**Using experienced researchers.** In addition to using case studies, a number of respondents noted the value of involving faculty researchers in class discussions. Having practitioners as speakers, panelists, and facilitators provides rich opportunities for understanding the context of RCCR and seeing how in-the-trenches researchers approach ethically difficult issues that arise.

One participant described additional benefits of involving practitioners in RCCR training:

We thought it would be more effective in some ways to see how investigators who the class members are actually working with or see as mentors . . . grapple with ethical issues. We also thought it would be a way of spreading the ethics message a little more widely by getting some of these more senior people to actually step back and think about what they're doing. (#6)

Another interviewee offered a similar rationale for involving former students in current teaching efforts:

I thought it would be particularly good to involve the students from former years, . . . it kind of creates an expectation of ethics and ethical behavior, . . . because we would get more people involved, and this would become a normal discussion. (#26)

Such a "normal discussion" may promote a culture of responsibility in clinical research.

**Calibrating the timing.** When is the most "teachable moment" for students? At what point in the overall experience of students is it most appropriate to include RCCR training? Several respondents recommended that training be offered early and often, though the reality of their institutions might not necessarily make this a realistic goal. Two participants' comments are illustrative:

You want to get them early enough that they're new at it and that they've got the ideas percolating in their minds as they're starting to get onto the wards. . . . We need something more intensive, we need small groups, [and] we need something at different times in their training. (#47)

Doing it one time seems silly to me. To require human subjects protections training one time and then for the next 30 years of your career you never had to go to another thing—I'm not quite sure what the point of the first one is if you're going to do it that way. . . . But, I do think that every couple of years an investigator needs to have attended at least an hour of training somewhere, . . . something related to human subjects protections so that there's going to be ongoing training. (#20)

In addition, the curriculum must be offered when students can realistically access it—for example, in the evening, or very early morning before their clinical duties begin, or at a point in their careers when they are on campus and not traveling for interviews. One interviewee suggested that ethics training be integrated into preexisting meeting times or lunch periods so that instructors don't need "to add something on the plate of the investigators and research personnel" (#20). A limitation on time has been a major impetus for recent efforts toward developing online courses.

**Designing with the goal in mind.** Course design depends on its educational objectives. The goals may be different for different audiences and in different contexts. As one participant stated,

If the goal is to help them know how to give informed consent, then I would have them have standardized patients and practice giving informed consent. If the goal is to help them understand the theory, then I would have to give them reading. If the goal is to get them to think about topics that they hadn't thought about and then sort of take them into

consideration, then I would do . . . journal clubs and small-group article discussions. So the best depends on what my educational objectives are. (#29)

Thus, instructors must be clear about their goals in order to design curricula appropriately. In general, participants agreed that one common goal ought to be to promote reflection on the ethics of clinical research, not simply compliance with relevant policies.

**Determining effectiveness.** Despite endorsing the methods described above, instructors we interviewed commented that they did not have clear standards to measure success. Typically, they administered only subjective evaluations. Thus, they largely lacked objective measures to support their recommended strategies. For example, one respondent acknowledged that such strategies may not work for all students. This instructor felt that case studies

may not work as well for foreign-born biology grad students who don't speak very much English. I could be wrong. They might do better with an online module that they could take really slowly, and, perhaps, have translated. (#21)

### Useful materials for teaching RCCR

Though many of the interviewees used standard texts in their classes, most participants commented that they invest a good deal of time and energy in compiling their own resources, sometimes to supplement textbooks and sometimes as stand-alone compendia in place of such texts. They gather relevant journal articles. Many instructors write their own cases, often based not only on the literature, but also on their own experiences conducting research or serving on IRBs. As described above, some also have their students construct cases. Several commented that they had developed supplemental Web sites for their courses, where they would post links to useful resources for use throughout the course. Appendix 1 summarizes the various resources described by the participants.

### Instructional needs

We asked participants to identify institutional supports for and barriers to their RCCR teaching efforts. Participants provided us with a list of their needs. They identified items on the list as supports if their institutions met these

needs, and as barriers if their institutions failed to meet them. The most commonly cited need was sufficient time to devote to their work. One interviewee remarked:

Money seems to be the answer to everything but, quite frankly, the biggest problem we have in academia right now is that faculty get asked to do things like this and they're not provided the time to do it. You know, their clinical requirements don't change, their research expectations don't change. It's just an add-on. So when I'm asked to do this training session, it comes out of my time. That's not the way to get a good, vibrant . . . education process. (#20)

In addition to this concern about the individual instructor's time, participants acknowledged that the work must be shared among faculty members. Thus, the workload must be reasonable if the work is to be done well (or at all).

Participants also highlighted the need for enhanced cooperation. As one participant put it,

The efforts to teach RCCR are really sort of scattered and inchoate. So, for example, other departments that have their own training grants and so forth, will be doing similar sorts of things within their own department. We have a physician–scientist training program and even a master's degree program that has its own ethics component. We are trying to . . . unify those efforts. (#30)

Cooperation—both within and between institutions—allows for sharing resources, strategies, and expertise. RCCR training efforts would likely benefit if institutions and professional societies committed to facilitating such cooperation.

Other commonly cited needs included adequate funding for instructors and instructional resources, support from institutional leadership (“not just in terms of funding, but in terms of attitude and emphasis” [#39]), collegial assistance (e.g., guest lectures, help with case study development, sharing resources), technical support (e.g., with course Web sites or PowerPoint presentations), and opportunities for their own continuing education.

Finally, respondents agreed that RCCR education should be required:

The unfortunate thing is, I think, that if it's not required, nobody comes. That's just a reality. The people you get are the

people who are already interested enough that they probably don't need the training. You don't get the people who really need to be there. So, I think it has to be mandatory. (#20)

Well, I think there probably should be compulsory courses for people who do clinical research. . . . You don't let somebody loose and do research on people before they really . . . you have to have some kind of course work . . . in research ethics. (#39)

## Discussion

Our findings demonstrate that experienced instructors use an array of methods and cover a broad range of topics when conducting training in RCCR. Clearly, one size doesn't fit all of the circumstances in which RCCR training is conducted. Rather, RCCR has been tailored to fit the unique institutional settings and trainees in question, often involving creative approaches. Such approaches should be of use to those planning RCCR training in different settings.

Despite this diversity of approaches, the respondents expressed considerable agreement on the *recommended* strategies for such teaching. Unfortunately, many participants felt that institutional or organizational obstacles hinder the full application of these strategies. For example, limits on time allotted for instruction might force an instructor to use a didactic teaching style despite preferring a more interactive strategy. Thus, our respondents expressed strong views, not only about what instructors should do, but also about what institutions must do to offer appropriate RCCR education and so promote a culture of responsibility in clinical research.

The findings from this study should be interpreted with some limitations in mind. The participants may not represent the overall RCCR teaching population. We reached RCCR teachers through the ASBH, but there is no systematic information about who teaches RCCR either nationally or among ASBH members. As with many surveys, selection bias may play a role. Further, particular respondents may have interpreted study questions differently. For example, in the online survey, one question asked respondents to check topics covered in their courses. At least

one respondent felt that if the course “didn't focus much” on the issue, but still addressed it, then the topic should not be checked. Others seemed to check any and all items touched on, however briefly. Finally, there was little evidence of formal measures participants used to support their recommended strategies, both in terms of the lack of consistent and rigorous evaluations of training opportunities in RCCR and, ultimately, in how this training translates into the responsible conduct of clinical research. Although the considerable degree of agreement among participants lends credence to their recommendations, further research is required to evaluate these recommendations and thus to draw decisive conclusions about best practices for RCCR training.

Despite these limitations, our findings provide much needed information about the development of RCCR training courses. Our participants' insights provide useful, if provisional, guidance to instructors and institutions faced with the task of providing RCCR training. In addition, this study suggests that the current societal mandate to improve the conduct of clinical research may be undermined by institutional obstacles to meeting the needs of knowledgeable instructors. If so, then the symbolic commitment to responsible research suggested in policy may not bear fruit in the form of actual improvements in the moral climate of clinical research. This study suggests the need to invest in RCCR training, study outcomes of such training, and develop mechanisms to insure the quality of the instruction. Our research and its conclusions offer a preliminary roadmap that instructors and policy makers at the institutional or national level might follow to achieve this goal.

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## Acknowledgments

The authors wish to acknowledge Tyson B. Rogers, MS, of the Department of Medicine, University of Minnesota, for his valuable assistance with statistical analysis.

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## Appendix 1

### Useful Resources for Instructors in the Responsible Conduct of Clinical Research (RCCR)

#### Textbook Materials

- Barnbaum DR, Byron M, eds. *Research Ethics: Text and Readings*. Englewoods Cliffs, NJ: Prentice Hall; 2000.
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