

## ***Resources for Instruction in Responsible Conduct of Research***

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***Keywords: Instruction, Internet, Research ethics, Responsible conduct of research, RCR, World Wide Web***

In recent years it has become clear that, despite its importance, training in ethics, standards, and responsible conduct is too frequently minimal or absent in academic science. This deficit is being corrected in part by the requirement that fellows funded by National Institutes of Health (NIH) training grants receive such instruction. This requirement has been important to the development of a variety of outstanding texts now available (1-8) and a number of very effective, thoughtful programs developed across the country. However, no network provides ready communication about the goals, resources, tools, or methods for such programs. As a result, the design and implementation of a new program in responsible conduct of research (RCR) training can be frustrating if not intimidating.

It can be difficult to pull together material for a new RCR program. Unfortunately, such effort is frequently duplicated even within the same institution and the resulting RCR instruction is uneven in quality, topics covered, and audience reached. In addition, it appears that the most likely audience for these programs has been limited to only those NIH trainees required to take part. This is contrary to the goal that such training is best met by a program that reaches the broad spectrum of the academic community including staff, undergraduates, medical students, pre- and post-doctoral fellows, and both junior and senior faculty. However, with the rapid changes in access to the Internet, the technology is now available to make formats, examples, contacts, and resources immediately available to any institution interested in providing effective RCR instruction.

The Internet is now being used for a variety of purposes relevant to RCR instruction (9-17). In just the last couple of years, these resources have evolved rapidly in both form and content. Many institutions have created web sites that provide considerable content as well as lists of links to other sites (9-10), typically in the area of ethics. In addition, many universities now have course materials posted on the web (11-13) and in some cases Internet-based courses, designed to be run without traditional classroom meetings (14,15). Finally, web-based information is available on programs such as the "Survival Skills and Ethics" (16) and "Teaching Research Ethics" (17) workshops for teaching about the teaching of responsible conduct of research. All of these resources provide important contributions, but diverse audiences, differences between disciplines, and the frequency of significant new developments, all minimize the value of any one approach to RCR instruction. The proposed alternative is a continually evolving web site.

A web site dedicated to resources on instruction in the responsible conduct of research could provide national access to the most effective programs, materials, and methods for such training. The long-term goal would be to improve the quality and extent of RCR instruction. Such a site would not only make it possible for virtually any institution to develop an RCR program, but would also increase general awareness about what is being done, and what can be done, to enhance instruction in RCR. It is intended that this site would complement, not replace, other tools for RCR programs (1-17). Given the ongoing NIH requirement for training grants to include instruction in RCR and the proposed extension of this requirement to all research staff working on PHS-supported projects, many institutions need help to either extend limited existing programs or to develop new programs. However, even in the absence of federal requirements, it should be enough to know that access to proven materials and methods for RCR instruction can only help to foster responsibility in the conduct of research.

### **Methods**

The core of the web site was first assembled from materials already available for courses taught at the University of California in San Diego, Francis Macrina's course at Virginia Commonwealth University and his book on "Scientific Integrity," and course materials under development at the University of Minnesota.

The site was initially designed to cover nine topic areas: (1) Getting started; (2) Defining the goals of an RCR program; (3) Elements of an RCR program; (4) Guidelines, requirements, and procedures; (5) Resources; (6) Case studies; (7) RCR programs; (8) Contacts; and (9) Evaluating an RCR program. The plan was that these primary divisions would be subdivided into topics generally considered to be relevant to responsible conduct of research (e.g., conflict of interest, use of animals in research, and criteria for authorship). Using this framework for the content available in the authors' institutions, the initial goals were to design and implement a framework for the web site, insert materials from the authors' institutions, and annotate the resources.

After completion of the first steps of the project, the web site was to be improved through an iterative process, including three phases of external reviews, plus soliciting of suggestions

for additional materials. For this review phase, the primary goals were to solicit new materials from other institutions, modify the framework of the site as needed to accommodate the new resources and reviewer suggestions, annotate the resources, and publicize the site.

For evaluation of the web site, reviewers were asked to rank various aspects of the site's form and content in a brief online form. Numerical rankings were to be scored using a scale of 1 to 5 (1=very low, 2=low, 3=average, 4=high, 5=very high). Additional questions asked for specific suggestions to improve the web site, including recommendations of material to be added.

### **Results**

The first phase of this project was to develop a web site framework for presenting resources on instruction in the responsible conduct of research. Beginning in September of 1999, work on the web site began at the University of California, San Diego with ongoing assistance from collaborators at Virginia Commonwealth University and the University of Minnesota. During the initial months, the web site evolved through several different formats until a version was considered ready for external review. In July of 2000, the first phase of external review was begun. The three planned phases of review were completed by November 1, 2000.

The first external review was based on a limited release of the web site to four reviewers (two from government agencies and two from non-governmental organizations). In a series of questions about web site form and content, scores averaged between 3.25 and 4.75 with medians between 3 and 5. The lowest scores were generally assigned to the appearance and navigability of the web site. Several valuable suggestions were made for future improvements, but one—ease of navigation—was sufficiently important to address before the next phase of review. Based on this concern, the structure of the web site was considerably modified to provide the user with a linear arrangement of topics. This and other changes were completed by the beginning of August 2000.

For a second external review, 13 people were asked to participate. One of the 13 did not respond to the invitation, three declined because of conflicting commitments, but two recommended other choices for reviewers. Ultimately, of nine who agreed to review the site,

QUESTIONS	AVERAGE	MEDIAN
1. CONTENT		
A. How would you rate the choices of topics covered?	5.0	5.0
B. How would you rate the quality of information provided?	4.6	5.0
2. NAVIGATION		
How would you rate the ease for navigating within the Web site?	4.2	5.0
3. APPEARANCE		
How would you rate the appearance of the Web site?	3.8	4.0
4. OVERALL		
A. How would you rate the likelihood you would recommend this resource for someone developing a new training program?	4.6	5.0
B. How would you rate the likelihood you would recommend this resource for someone improving an existing program?	4.8	5.0

Table 1. Second phase of external review (6 reviewers). Using a scale of 1-5 (1 = very low, 5 = very high), the reviewers answered the following six questions.

three failed to meet the deadline. The six reviewers who responded were from two public universities, one private university, two government agencies, and one non-governmental organization.

A summary of the average and median of the second phase of reviewer evaluations is provided in Table 1. The reviewers were extremely positive about the content of the web site (averages of 4.6 to 5.0). Compared to the previous round of review, these reviewers were also more positive about navigation (4.2 vs. 3.25-3.75). Although considered acceptable, no reviewer scored appearance of the web site as a 5. In addition, the reviewers offered many practical suggestions for improvements in content, navigation, and appearance.

A third external review was begun in September of 2000. A total of 48 people were asked to review the web site by early October; 31 responded that they had the time and would be

willing to do so. Of those, reviews were completed by 23 reviewers (16 public institutions, 4 private institutions, 2 government agencies, 1 Canadian government agency).

A summary of the average and median of the third phase of reviewer evaluations is provided in Table 2. Evaluation rankings were generally in the range of 4 to 5. Lowest scores were for the appearance of the web site (average=3.8) and highest scores were for the likelihood that the reviewers would recommend this web site as a resource for someone developing a new training program (average=4.8). The reviewers were again generally positive, but several made excellent suggestions for changes in structure and content to the site. Few comments were repeated across reviewers. Major areas of criticism included:

1. Content: One reviewer was looking for a pre-packaged RCR course along the lines of the web-based tutorials for training

QUESTIONS	AVERAGE	MEDIAN
1. CONTENT		
A. How would you rate the choices of topics covered?	4.4	4.0
B. How would you rate the quality of information provided?	4.1	4.0
2. NAVIGATION		
How would you rate the ease for navigating within the Web site?	4.0	4.0
3. APPEARANCE		
How would you rate the appearance of the Web site?	3.8	4.0
4. OVERALL		
A. How would you rate the likelihood you would recommend this resource for someone developing a new training program?	4.8	5.0
B. How would you rate the likelihood you would recommend this resource for someone improving an existing program?	4.5	5.0

Table 2. Third phase of external review (23 reviewers). Using a scale of 1-5 (1 = very low, 5 = very high), the reviewers answered the following six questions.

researchers working with human subjects. As this reviewer observed, this web site does not provide such a course.

2. **Format:** The most frequently voiced concern was that the background (a grid similar to a lab notebook page) was distracting.
3. **Audience:** It wasn't clear to some reviewers who the audience (i.e., instructors of RCR courses) was for this web site.
4. **Structure:** Several reviewers failed to find key elements of the web site (e.g., the examples of courses) and some pointed out confusion about the structure of some of the sections (esp. resources and cases). Related to this problem, a couple of the links did not work, or did not work as expected.

Several of the reviewers were quite supportive of the web site, for example:

"The choice of topics to be covered in teaching research ethics is excellent. I particularly think it is useful that 'minimal instruction' is defined for each of the topics and that more advanced versions of the units are also suggested. This will be quite helpful to faculty who are just beginning to teach RCR, and who want to know what is the minimum level of instruction they need to meet."

"I think the site looks great. It is very well organized. It will be especially useful for newcomers."

"Best collection of materials related to RCR I have found. The logical progression of steps should make it easy to develop or improve courses without becoming overwhelmed by the task at hand. Linked pages were relevant and provide materials for inspiration and contrast."

"This is a very strong site and I learned a lot just skimming. The links for case studies and analysis of instructional delivery options were quite good."

"This is a great program. I think its strongest feature is the way it brings together a wealth of material in a useful and usable form."

Based on the reviewer comments, further significant changes were made to the structure of the web site. As of its release, the structure of the web site was designed around five topic areas:

Goals (Goals for RCR instruction), Content (Suggested RCR topics: Descriptions and reading lists), Format (Formats for RCR instruction: Descriptions and examples), Tools (Tools for RCR instructors: Texts, cases, and contacts), and Evaluation (Evaluation of RCR instruction: Overview and examples). After checking that the structure of the web site was consistent and that all links were active and accurate, the web site was released for public use on November 1, 2000.

### **Discussion**

As proposed, a new web site was developed to facilitate access to resources for instruction in the responsible conduct of research. With the support of constructive comments from external reviewers, an initial version of the web site was made available to the research community beginning on November 1, 2000. Based on reviewer comments, this web site will be of value both to those first developing programs of RCR instruction and also to those seeking to improve on existing programs of instruction.

To achieve the long-term goals for this web site, it will be necessary for the site to evolve both in terms of content and format. For this purpose, the authors intend to solicit the latest information about content and format of existing RCR programs nationwide. Further, it will be important to include mechanisms for ongoing evaluation of the merits of the resources listed on the web site and the web site itself. During this next phase, the primary goals will be to survey existing programs in RCR, solicit new materials from these institutions, continue modifying the framework of the site as needed to accommodate the new resources, and implement mechanisms for evaluating the effectiveness of the web site and the resources listed.

### **Acknowledgments**

The Office of Research Integrity (ORI) and particularly Alicia Dustira, Lawrence Rhoades, and Chris Pascal, all of ORI, are thanked for their encouragement and support for the initial development of this web site. The University of California, San Diego is thanked for its support of the Project Director (MWK), helping to make this project possible. In addition, the generous contributions of time and suggestions of the 33 external reviewers are gratefully acknowledged. This work was supported by a contract from the ORI to UCSD (contract #99T07035001D)

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16. Survival Skills and Ethics, University of Pittsburgh: <http://www.edc.gsph.pitt.edu/survival>
17. Teaching Research Ethics, Indiana University: <http://www.indiana.edu/~poynter/tre.html>

