Scientific Integrity
Publisher's Note: Scientific Integrity: Text and Cases in Responsible Conduct of Research (Fourth Edition) is intended to serve as a text for courses and workshops on responsible conduct in scientific research. The text is not meant in any way to serve as a set of guidelines, rules, or statements officially endorsed by the American Society for Microbiology or any other scientific organization or institution.

The case studies used throughout this text are hypothetical and are not intended to describe any actual organization or actual person, living or dead. The opinions in the text, express or implied, are those of the authors and do not represent official policies of the American Society for Microbiology.

Cover Image: Taken in 2009 by a camera onboard the National Aeronautics and Space Administration (NASA) Hubble Space Telescope, the image is that of a celestial body designated NGC 6302, a "planetary nebula." It is more commonly known as the Butterfly Nebula because of its distinct butterfly shape. Originally, the term planetary nebula had been used to describe objects, viewable with binoculars or a small telescope, that have a roundish appearance similar to a planet. However, as revealed by larger telescopes, planetary nebulas are really stars that have ejected much of their mass during a destructive phase of their evolution that will lead to their demise. The star in NGC 6302 occurs at the juncture of the two butterfly "wings" and cannot be seen in the photograph because it is shrouded in dust. The ejected gases and ultraviolet radiation emanating from the dying star create glowing material that defines the butterfly shape. More information may be found at: http://www.nasa.gov/mission_pages/hubble/multimedia/ero/erongc6302.html.

The cover image was downloaded from the NASA web site. It is not copyrighted and is considered in the public domain by that agency. NASA is hereby gratefully acknowledged for its use. NASA’s image use policy may be found at: http://www.nasa.gov/audience/formedia/features/MP_Photo_Guidelines.html#U7x7svldWCI

Copyright © 2014 American Society for Microbiology. ASM Press is a registered trademark of the American Society for Microbiology. All rights reserved. No part of this publication may be reproduced or transmitted in whole or in part or reutilized in any form or by any means, electronic or mechanical, including photocopying and recording, or by any information storage and retrieval system, without permission in writing from the publisher.

Disclaimer: To the best of the publisher’s knowledge, this publication provides information concerning the subject matter covered that is accurate as of the date of publication. The publisher is not providing legal, medical, or other professional services. Any reference herein to any specific commercial products, procedures, or services by trade name, trademark, manufacturer, or otherwise does not constitute or imply endorsement, recommendation, or favored status by the American Society for Microbiology (ASM). The views and opinions of the author(s) expressed in this publication do not necessarily state or reflect those of ASM, and they shall not be used to advertise or endorse any product.

Library of Congress Cataloging-in-Publication Data
Macrina, Francis L., author.
Scientific integrity : text and cases in responsible conduct of research / by Francis L. Macrina, Edward Myers Professor of Dentistry and Vice President for Research, VCU Philips Institute for Oral Health Research, Virginia Commonwealth University, Richmond, Virginia. —Fourth edition.
pages cm
Q180.55.M67M33 2014
174'.95—dc23 2014017024
doi:10.1128/9781555818487

Printed in the United States of America
10 9 8 7 6 5 4 3 2 1
Address editorial correspondence to: ASM Press, 1752 N St., N.W., Washington, DC 20036-2904, USA.
Send orders to: ASM Press, P.O. Box 605, Herndon, VA 20172, USA.
Phone: 800-546-2416; 703-661-1593. Fax: 703-661-1501.
E-mail: books@asmusa.org
Online: http://www.asmscience.org
For Mary

and

Laurel, Mike, Dylan, and Megan
Frank, Neeley, Lauren, and Nicholas
In memory of

My mentors
John J. Quinn 1931-2009
Elias Balbinder 1926-2011

and

My colleague, and pioneer in research ethics education
Karen M. T. Muskavitch 1953-2009
Contributors xiii
Foreword xv
Michael J. Zigmond and Beth A. Fischer
Preface xxv
Acknowledgments xxviii
Note to Students and Instructors xxix
A Website Companion for Scientific Integrity: Text and Cases in Responsible Conduct of Research, Fourth Edition xxxii

Contents

chapter 1  Methods, Manners, and the Responsible Conduct of Research 1
Francis L. Macrina
Overview • Scientific Misconduct • Responsible Conduct of Research • Conclusion • Discussion Questions • Resources

chapter 2  Ethics and the Scientist 25
Bruce A. Fuchs and Francis L. Macrina
Overview • Ethics and the Scientist • Science as a Profession • Underlying Philosophical Issues • Utilitarianism • Deontology • Values of the Scientific Community • Critical Thinking and the Case Study Approach • Moral Reasoning in the Conduct of Science • Conclusion • Discussion Questions • Case Studies • Principles and Responsibilities of Research Conduct • Resources

chapter 3  Mentoring 53
Francis L. Macrina
Overview • Characteristics of the Mentor-Trainee Relationship • Choosing a Mentor • Foundations of Mentoring • Diversity, Research, and Research Training • Learning Mentoring Skills • Conclusion • Discussion Questions • Case Studies • Resources
chapter 4  
**Authorship and Peer Review**  
*Francis L. Macrina*

Scientific Publication and Authorship • The Need for Authorship Criteria • Instructions for Authors • Authorship: Definitions, Duties, and Responsibilities • Peer Review • Publication’s Changing Landscape • Conclusion • Discussion Questions • Case Studies • Resources

chapter 5  
**Use of Humans in Biomedical Experimentation**  
*Paul S. Swerdlow and Francis L. Macrina*

Overview • Are You Conducting Human Subjects Research? • The Issue of Informed Consent • IRBs • The IRB and the Informed Consent Issue • Research Exempt from the Federal Regulations • The IRB and Expedited Review • Human Experimentation Involving Special Populations • The Health Insurance Portability and Accountability Act (HIPAA) • Fetal Tissue and Embryonic Stem Cell Research • Conclusion • Discussion Questions • Case Studies • The Declaration of Helsinki • Resources

chapter 6  
**Use of Animals in Biomedical Experimentation**  
*Bruce A. Fuchs and Francis L. Macrina*

Introduction • Ethical Challenges to the Use of Animals in Research • Practical Matters: Constraints on the Behavior of Scientists • A Continuum of Realities • Conclusion • Discussion Questions • Case Studies • Resources

chapter 7  
**Competing Interests in Research**  
*S. Gaylen Bradley*

Introduction • Conflict of Effort • Conflict of Conscience • Conflict of Interest • Managing Competing Interests • Conclusion • Discussion Questions • Case Studies • Resources

chapter 8  
**Collaborative Research**  
*L. Michelle Bennett and Francis L. Macrina*

Overview • Drivers of Collaborative Research • A Case in Point • Challenges of Collaborative Research • The Nature of Collaboration • Collaborative Agreements and Institutional Commitment • Fundamentals for Successful Team and Collaboration Dynamics • Mentoring in the Era of Team Science • Diversity • Authorship • Data Sharing, Custody, and Ownership • Managing Conflict and Promoting Disagreement • Collaborations with Industry • Collaboration with International Partners • Conflict of Interest • Miscellanies • Conclusion • Discussion Questions • Case Studies • Resources
## Contents

### Chapter 9
**Research Data and Intellectual Property** 287
*Thomas D. Mays and Francis L. Macrina*

- Introduction
- Research Data
- Rights in Tangible Personal Property
- Trade Secrets
- Trademarks
- Copyrights
- Patents
- Patent Law in the Age of Biotechnology
- Seeking a Patent
- Conclusion
- Discussion Questions
- Case Studies
- Authors’ Note
- Resources
- Glossary

### Chapter 10
**Scientific Record Keeping** 329
*Francis L. Macrina*

- Introduction
- Why Do We Keep Records?
- Defining Data
- Data Ownership
- Data Storage and Retention
- Tools of the Trade
- Laboratory Record-Keeping Policies
- Record-Keeping Practices
- Electronic Record Keeping
- Conclusion
- Discussion Questions
- Case Studies
- Resources

### Chapter 11
**Science, Technology, and Society** 361
*Cindy L. Munro and Francis L. Macrina*

- Responsibilities of Scientists to Society
- rDNA Technology
- Genetic Technology
- DURC
- Conclusion
- Discussion Questions
- Resources

### Appendix I
**Surveys as a Tool for Training in Scientific Integrity** 387
*Michael W. Kalichman*

### Appendix II
**Student Exercises** 413

### Appendix III
**Standards of Conduct** 429

### Appendix IV
**Sample Protocols for Human and Animal Experimentation** 445

### Appendix V
**Example of a U.S. Patent Specification** 489

### Appendix VI
**Laboratory Notebook Instructions** 503

### Appendix VII
**Safe Laboratory Practices Resources** 509

Index 517
Contributors

L. Michelle Bennett, Ph.D.
Deputy Scientific Director, Division of Intramural Research
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland

S. Gaylen Bradley, Ph.D.
Dean Emeritus, Basic Health Sciences
Virginia Commonwealth University
Richmond, Virginia

Bruce A. Fuchs, Ph.D.
National Institutes of Health
Bethesda, Maryland

Michael W. Kalichman, Ph.D.
Director, Research Ethics Program
& Professor of Pathology
University of California, San Diego

Thomas D. Mays, Ph.D., J.D.
Counsel for Intellectual Property
Bureau of Competition
Federal Trade Commission
Washington, District of Columbia

Cindy L. Munro, Ph.D., R.N., ANP-BC, FAAN, FAANP, FAAAS
Associate Dean of Research and Innovation,
Professor
University of South Florida College of Nursing
Tampa, Florida

Paul S. Swerdlow, M.D.
Professor of Medicine, Oncology (Hematology/
Oncology) and Pediatrics
Wayne State University School of Medicine
Detroit, Michigan
Like Frank Macrina, the author of this outstanding textbook, we have been teaching students, postdoctoral fellows, faculty, and staff about the responsible conduct of research (RCR) for many years, and we welcome the opportunity to share some of what we have learned during that time. Neither this short essay nor the book itself is a manual on the responsible conduct of research. You can find such manuals—many professional societies have them, and federal agencies do, too. And, yes, Dr. Macrina will introduce you to some rules and regulations, generally agreed-upon standards, and even some laws. But mostly you will be given the opportunity to think—to think about what it means to act responsibly.

There are several reasons for focusing on thinking rather than simply memorizing rules. First, active engagement is critical to promoting real understanding. Second, acceptable standards often differ with the research culture and thus can vary with geography, discipline, and department and even among individual laboratories. Third, important issues are always evolving. Ask yourself, which issues of significance to research today were not even considerations a generation ago? Consider, for example, that the use of Photoshop® to “enhance” a figure, or the cutting and pasting of text found on the Internet, could not have become issues until those tools became available in the early 1990s. Which other issues have recently emerged? And what do you imagine will be the issues that will confront you a decade from now? Will it be the automatic genetic profiling of each individual at birth? The ability of one person to monitor the thought processes of another?

Before you go any further, we invite you to take a moment to make a list of what you think are the central issues in RCR and then see how we and Dr. Macrina do. Did we miss some issues you think are important? If so,
raise the issues among your colleagues. And write to the author—you may play an important part in the development of the next edition!

In this brief Foreword we deal with two issues. We begin by considering how instruction might best be provided. We then analyze some of the federal and institutional guidelines that have played an important role in promoting the introduction of RCR training into academic programs, suggesting that they are an important driving force for ethics education but also that they in part have led to some of its most serious—and contentious—problems.

Teaching RCR: how, who, and when?

We all learned at an early age to pay more attention to what people do than what they say. One of our favorite cartoons is by Edward Argo. It portrays a young child standing in the corner facing the wall and saying to his stuffed animal friend, “The same people who told me the stork brought me are making me stand here for lying.” You can substitute your own favorite example of the discrepancy between words and actions in lecture halls and the workplace. This is why the “how” of RCR instruction is so much more important than the precise details of what is included in the curriculum.

How to teach? The most common approach for teaching most things, including RCR, is by lecturing. And certainly that can be a useful method for delivering large amounts of material to sizeable groups of individuals. But all too often lectures quickly devolve into an exercise in dictation, providing little opportunity for engagement with the material and real learning. Should this be pointed out to an instructor, the response is often “I can’t take time for discussion, there is just too much to teach!” We, too, have been guilty of this mindset, forgetting the extensive research indicating that little of the material delivered in a purely lecture format is retained.

There are many other problems with that approach, as well: the instructor may not be sufficiently knowledgeable in the subject matter or skilled in the art of teaching; the composition of the class may be highly heterogeneous and thus not amenable to a “one size fits all” approach; the material may be presented out of context and, thus, its significance may be difficult to grasp or even undermined. Lecturing is not an effective way of teaching anything, let alone research ethics. We describe an alternative approach below.

Who should teach? The topic of ethics immediately brings philosophers to mind, and indeed philosophers can play a valuable role in promoting research ethics. They can help both teachers and trainees to understand ways of thinking about ethical problems. But we do not believe that philosophers are effective as the primary instructors of courses on this critical
subject. For this, one needs people with experience in the practice of research, or at least individuals working in a partnership with active researchers. And these RCR instructors must treat their task as they would a research project: by thinking deeply about the subject matter, reading the literature, seeking advice from others, developing and testing hypotheses about what will be effective, and finally getting feedback on their own performance as well as the impact they are having on their trainees.

Instruction that does not involve active researchers is unacceptable for at least two reasons. First, the message provided by courses that do not involve investigators is that such individuals either do not know enough about RCR to teach it, or that they do not feel it is worth their time to do so. Second, non-scientists can be dangerously out of touch with the everyday reality of practitioners. For example, we have heard instructors say that all authors of any research paper must have reviewed all of the data and be able to explain all of the methods used. In theory this sounds entirely reasonable. But a moment’s thought will make clear that such a rule is inconsistent with the complex, collaborative, and interdisciplinary nature of most of today’s research.

In addition to those who direct formal courses in RCR, research group directors are another critical component of the instruction. Whatever their intention when they accepted jobs at educational institutions, all too often these individuals come to view the members of their teams largely as research assistants. Thus, anything that takes their lab members out of the lab is a distraction from the task at hand, and RCR training often tops the list of those “distractions.” We understand this; advancement in academia is typically based on research productivity, not on mentoring. Yet, it goes without saying (though we will say it), that irresponsible research can never be good research. Research that involves cutting corners or using erroneous statistical tests, not to mention intentionally manipulating data, may be at the heart of many failures to replicate published studies that have recently been a focus of much discussion in both the professional and the lay literature (see, for example, references 1 and 2). Moreover, whereas courses on RCR—when they are offered—may involve less than a dozen hours of instruction, often at the outset of a training program, research advisors influence members of their groups for thousands of hours over many years. And as we have already implied, it is the example set by research directors and others in the academic environment that really counts. Moreover, it is not only the trainees that they influence, it is all members of their research group.

This brings us to the overriding issue of “climate.” As one would expect, a corollary of the importance of setting a good example is that the climate in which research is done has a significant impact. Some 20 years ago, Melissa Anderson, Karen Louis, and Judith Swazey set out to study this topic as part of the Acadia Institute’s Project on Professional Values and Ethical
Issues in the Graduate Education of Scientists and Engineers. They found that graduate students who were socialized in departments in which the culture was more “caring” (e.g., one that promoted collaboration versus competition among individuals in a laboratory and was made up largely of faculty who showed an active interest in the career development of their students) reported witnessing fewer incidents of misconduct than did students in less caring environments (3). Studies conducted since then continue to echo those findings (e.g., references 4 and 5).

When should instruction occur? As we have noted, instruction in RCR is typically provided as brief, required workshops or courses taken at the very beginning of a training program. The participants in such courses are usually limited to graduate students, though sometimes postdocs are expected to attend as well. And the impact of the course on participants is typically either not evaluated or is done so through a short essay. There is nothing good about this approach; indeed, it is destructive. The message is obvious: “This is something we unfortunately must require you to do, so let’s get it over with as quickly as we can, and then we can move on to the important things.” Consider a very different model:

1. Upon arrival at an institution, all individuals—be they students, postdocs, faculty, staff, or administrators—are introduced to the importance of RCR, their own role in ensuring that it occurs, and some of the major issues. (Time: 1 to 2 hours.)

2. Next, all individuals involved in the research enterprise engage in a weekly seminar in which some of the key topics are explored during discussions that are facilitated primarily by active researchers and are usually focused on specific cases. (Time: 1 hour × 8 to 12 sessions.)

3. At the same time, RCR appears in the core curriculum. When an instructor discusses an issue of basic science, he or she might raise issues of fabrication or falsification of data, perhaps by discussing a real case in which that occurred. Likewise, when describing a clinical condition, the class might discuss the role of informed consent or genetic counseling. (Time: 15 minutes every couple of weeks in every course, totaling 12 hours in a curriculum involving 6 courses.)

4. Finally, we move into our workspaces, be they a lab, faculty, or administrative meeting. The role of instructor now gradually shifts to the trainee, staff member, faculty member, or administrator. Ethics cases of direct relevance to the tasks at hand continue to be discussed, with the cases constructed and/or led by different members of the group. (Time: 1 hour × 2 to 3 sessions per year for the duration of an individual’s involvement in that unit, say a total of 10 hours over 5 years.)

Now, add it up: It comes to at least 30 hours over 5 years. “Are you kidding?” we hear the faculty saying. “I only get 2 hours to teach my students
about RNA editing or the Nernst equation or [fill in the blank], and you want me to spend 30 hours talking about ethics?!” But teaching about a specific topic in biology, math, or virtually any other discipline is not the right analogy. In fact, no one content area provides the right comparison, for what we must ultimately achieve through RCR education is the development of a complex skill: that of being able to reason through an ethical issue, one that often does not even have a “right” answer.

A far better exercise is to compare approaches for teaching RCR with the way in which we teach our trainees how to critically evaluate the scientific literature in their area of research. This is not accomplished in a 1-hour or even an 8-hour block. We begin by introducing the trainees to some of the basic concepts of the field. Next we have them participate in “journal clubs”—in-depth, small group discussions of an individual paper, simple papers at first, and then increasingly complex ones. The papers are presented, and the discussions led, by the trainees themselves. From there we move on to discussions of papers within the research group or even in one-on-one discussions between the lab director and a specific trainee. And these trainees soon begin to write their own papers, for which they must read and evaluate the literature. Finally, in the case of graduate students, we challenge them in preliminary exams, comprehensive exams, seminar proposal meetings, and the dissertation defense—all the time probing their understanding of the literature and their ability to justify their conclusions. As for postdocs, staff, and faculty, they get challenged, too. It happens each time they make a presentation. Yes, this process does involve learning some content—the proper organization of a paper, how to select the right statistical test, the importance of citing conflicts of interest. But mostly it involves the ability to critically analyze and then defend a position. Total time? Incalculable. Is doing research responsibly really not as important as being able to critically evaluate the literature and then defend your position?

The Role of Federal and Institutional Guidelines

The U.S. Federal guidelines on RCR training have played a critical part in the establishment of RCR programs. Before the National Institutes of Health (NIH) issued such guidelines, few training programs included explicit instruction in research ethics. Thus, the NIH guidelines have had a very positive impact by promoting RCR instruction for researchers. Yet, those same guidelines also have had the unintended effect of undermining the perceived importance of RCR, by turning what should—and can—be a valuable learning experience into one viewed as an exercise simply designed to ensure that a limited population meets a bureaucratic requirement delivered in isolation from the research enterprise.
Federal guidelines

Federal guidelines vary by agency, though it is not clear why this should be. Why, for example, does the U.S. National Science Foundation (NSF) insist that any institution that receives NSF funding have an institution-wide program of RCR training, whereas the NIH requires RCR training only for individuals supported by training and career awards? Other agencies have their own idiosyncrasies.

The NIH guidelines relating to RCR instruction appeared in 1989, and most training programs quickly learned that they were required to provide instruction in research ethics to at least a subset of their trainees. Since those initial guidelines, the NIH description of an acceptable RCR program has gradually evolved. Their most recent recommendations on how to fulfill their requirement for providing instruction in RCR (6) include an excellent set of “Basic Principles” that deserve to be read carefully as they include many of the key characteristics that we believe are critical to developing a good program.

The guidelines require that active researchers be involved in providing the instruction, and they specify a minimum number of hours of face-to-face instruction. But otherwise, they are not overly prescriptive. For example, the method of instruction is left open (except that online training does not count toward the required number of hours of face-to-face instruction). Moreover, NIH does not dictate the topics that must be addressed, but instead suggests nine content areas that “have been incorporated into most acceptable plans for such instruction.” Theirs is a fine list, though vague in regard to the scope of some topics. In particular, “research misconduct” is listed but never defined within the guidelines. But its major failing is in its definition of who must receive instruction: “individuals supported by any NIH training, research, education, fellowship, or career award” (6). This, of course, overlooks the great majority of graduate students and postdocs, both because the number of such NIH-supported positions is limited and because a great many trainees are not even eligible for those positions by virtue of their citizenship. It also omits staff, faculty, and administrators involved in the research endeavor.

In their 2009 guidelines, the NSF provided much less direction on the content of RCR training. They also indicated that “training plans are not required to be included in proposals submitted to NSF,” although they added “institutions are advised that they [the plans] are subject to review, upon request.” And most relevant to us, NSF specifies that the “institution must have a plan in place 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” (italics added) (7). Staff, faculty, and administrators are not
mentioned. Nor does NSF indicate the acceptability of exclusively relying on online instruction to meet their requirements.

Clearly, what is needed is a federal requirement—better yet, the readiness of institutions to establish programs without such a requirement—that merges these two statements and goes even further, implementing meaningful RCR training for everyone connected to the research enterprise. This was, in fact, recommended by the Commission on Research Integrity (CRI) established by then U.S. Secretary of Health and Human Services Donna Shalala in 1993 at the request of the U.S. Congress. The Commission was chaired by Kenneth Ryan and it issued its report, “Integrity and Misconduct in Research,” in 1995 (8). The 105-page document (including appendices and references) is worth reading even almost 20 years later. One recommendation deserves particular attention. Under the heading “Providing Education in the Responsible Conduct of Research” the report states:

“The Commission believes that, on balance, [required education in research integrity] should be more broadly implemented to ensure that, through such training, all individuals who perform research in institutional settings are sensitized to the ethical issues inherent in research. At present, the training is required only of recipients of institutional training grants, and does not reach all graduate, professional, and postdoctoral students or more senior researchers and other members of research groups, such as technicians. The Commission strongly believes that all of these individuals would benefit from participation. Providing such training is an important step toward creating a positive research environment that stresses the achievement of research integrity more than the avoidance of research misconduct.” (Italics added.) (8)

The role of professional societies and research institutions

Soon after the release of the Ryan report, the Federation of American Societies of Experimental Biology (FASEB) held a meeting attended by representatives from a large number of scientific societies to discuss the recommendations, which one of us attended (M.J.Z.). A major focus was the definition of misconduct and the topic of who should be trained. Our memory of the event is somewhat clouded by the passage of time, but the tenor of that discussion remains clear: the group was unambiguous in their criticism of the suggestion by Dr. Ryan (who was in attendance) and his Commission that such an “unfunded mandate” be put in place. A few years later, in a letter sent to the director of the Office of Research Integrity in 2000, Mary Hendrix, then the president of FASEB, wrote: “Students and trainees must have instruction in the responsible conduct of research. . . But the extension of this requirement to ‘all staff,’ including subcontractors and consultants, will result in an enormous involvement of time and resources.” (9)

The issue of “unfunded mandates” has recurred in other discussions of the Ryan report’s recommendation about RCR training. For example, in a
2009 letter to NSF, Richard Marchase, then the president of FASEB, wrote in regard to NSF’s new guidelines: “Even with access to educational materials, the implementation and administration of new training programs is not without cost. NSF should explore ways to fund these efforts so that additional training requirements do not burden institutions with new, unfunded mandates” (10). And, now 20 years after the Ryan Commission report was issued, the recommendation of universal training in RCR—which we wholeheartedly endorse—has not been made part of federal policy.

We recognize the many obligations shouldered by research institutions as well as professional societies. However, we also believe that providing training in RCR to everyone involved in the research enterprise is at the very core of ensuring that all research is done responsibly. That should not require any federal mandate, funded or not. Yes, institutions are burdened with an enormous number of requirements. They must ensure the value of the degrees they award by overseeing the curriculum and the process of certification. They must ensure fiscal responsibility. They are responsible for fulfilling the requirements for human and laboratory animal research and for laboratory safety. And that is just the beginning of the list. Thus, it is not surprising that many institutions view training in RCR as yet another requirement they need to check off, and that they often do only as much as they deem necessary to fulfill the requirement. However, research institutions should never define themselves in terms of the minimum needed to get by. Fulfilling the mandate to provide training in RCR cannot not be viewed as an end but as a means—a means to ensure the highest level of scholarship.

A Final Thought: How the Behavior of an Individual Can Ripple Across the Scientific Enterprise

There are many reasons to do everything that can be done to promote responsible research. Here we focus on one: the essential nature of trust and the cost of failing to meet that trust. The advancement of science requires trust—trust in the literature, in our collaborators, in the data we are handed, and most of all in ourselves. Each of us must know when to ignore an observation we make, when to repeat it, how to determine its significance, and when to publish. Observations in science sometimes come from an individual working on his or her own with little knowledge of what came before. But observations do not become advancements until others learn about them and are able to take them seriously, at least seriously enough to try to replicate them or to examine a corollary.

How much does a story in the media about research misconduct cost? Nothing? Wrong. It costs millions, maybe billions, of dollars. It leads individuals to stop contributing to foundations that support research.
voters to write their government representatives to tell them not to fund NSF or NIH. And it leads legislators to decide on their own that funding for research should be curtailed. Misconduct in science creates a breach of trust that threatens the viability of the research enterprise. It puts financial resources at risk and undermines the public’s trust in research findings. Perhaps worst of all, it can lead to students deciding that research is not for them.

The textbook you are about to enter is a tool—an extraordinarily valuable tool—to be used to foster responsible behavior. But, like any tool, it must be used in an educated manner in combination with other resources, including you. That is, it must be used responsibly. We wish you well.

Michael J. Zigmond and Beth A. Fischer
Pittsburgh, Pennsylvania

References

The first edition of Scientific Integrity: Text and Cases in Responsible Conduct of Research was published in 1995. The second and third editions each grew in length by approximately 20%, reflecting expansion in both scope and content. The Fourth Edition continues in this pattern. It is almost 30% larger than the Third Edition, and the addition of new and revised content arguably exceeds that of the second and third editions combined. The growth of the Fourth Edition has been driven by significant changes in the field of responsible research conduct. These changes have been evident in mandates, policies, laws, and other developments that continue to change the research landscape. Being aware of and understanding such change are critical elements needed to conduct research responsibly. Accountability and compliance as components of research conduct are essential to earning the trust of the public who, directly or indirectly, provide the resources for doing research that takes place in universities, research institutes, and other institutions in the not-for-profit sector.

Updated or new content may be found throughout this edition of the text, as noted in the following selected examples. Institutions, scientific societies, academies, and international organizations have published values that are expected to be held by researchers. And, the global research community has begun to articulate the values that undergird responsible research. Scientific organizations, societies, and institutions continue to develop guidance, recommendations, and tools that aim to increase the effectiveness of the mentor-trainee relationship. Authorship, peer review, and publication practices comprise a dynamic arena influenced by the open access movement, public access to federal grant-supported publications, postpublication review, and refined guidelines that speak to the
responsibility and accountability of authorship. A significant revision of the federal policies and practices that are required for the use of animals in research has been published and enacted. A new federal conflict of interest policy for researchers has been implemented, and new developments in the assignment of intellectual property have been defined by a ruling of the U.S. Supreme Court. Data sharing has been more specifically addressed by federal funding agencies, and the scientific record-keeping field continues to evolve in response to electronic technologies.

All of the Fourth Edition chapters have been updated and revised, and two in particular have undergone major rewrites. “Collaborative Research” (chapter 8) now reflects new developments and practices found in a growing body of literature that provides guidance on collaboration, interdisciplinary research, and team science. I was pleased to work with Michelle Bennett who coauthored this chapter with me. The last chapter in the text, now titled “Science, Technology, and Society,” replaces a chapter that appeared in the first three editions titled “Genetic Technology and Scientific Integrity.” My coauthor, Cindy Munro, and I used the Third Edition chapter as a basis to create the “Science, Technology and Society” chapter in this volume. Using both historical perspective and contemporary issues, we aimed to stimulate thinking on scientific research and the ways it connects with and impacts on society. In doing so, we hope to encourage scientists to think deeply about the societal responsibilities of their research and its applications.

As with previous editions, the content of the book is augmented by the inclusion of interactive exercises like short case studies, survey tools, and a play-acting scenario that explores authorship credit. Approximately 35% of the end-of-chapter cases are new or significantly revised. Appendixes III (standards of conduct) and IV (subjects protections protocols) contain new, updated documents, and Appendix VII is new to the book. This appendix presents resources relevant to safe laboratory practices.

Although the Fourth Edition of Scientific Integrity: Text and Cases in Responsible Conduct of Research covers a variety of topics related to the conduct of scientific investigation, it is not a rulebook for the researcher or trainee. Guidelines and policies, standards, and codes are presented and discussed so that readers will be aware that many of the relevant issues are influenced by both written policies and normative standards. Yet, the values of the individual take on major importance in doing scientific research. Scientists continually make judgments and decisions about their research. Whether the issue is the timely release of experimental materials to a colleague or decisions about authorship on a manuscript, personal and professional standards and values come into play. Thus, definitive, unambiguous advice on dealing with these and other issues cannot be taught in textbooks. To be sure, this book provides relevant content material on responsible research
conduct. But equally important, it provides tools to apply that knowledge. This book will challenge you to solve ethical research dilemmas in a variety of ways, most notably with case scenarios. Contemplation and informed analysis become the platform for learning in this setting. To echo the words of Michael Zigmond and Beth Fischer in the foreword, the ultimate aim of this book is to provide the opportunity to think: “to think about what it means to act responsibly.” The tools in this text provide material for such use in many of the venues and contexts found in the educational model that Zigmond and Fischer propose. In its case dilemmas, discussion questions, and other exercises, the book provides tools for challenging students at various points in their training programs. I have used such material in developing questions for both written and oral comprehensive exams and for dissertation defenses. Integrating the concepts of responsible conduct of research into our training infrastructure sends the message that learning RCR subject matter and mastering its use in solving problems is a critical part of continuing professional development.

The Fourth Edition of *Scientific Integrity: Text and Cases in Responsible Conduct of Research* aims to plant the seeds of awareness of existing, changing, and emerging standards in scientific conduct. Likewise, it provides the tools to promote critical thinking in the use of that information. My hope is that the book will set the stage for lifelong learning in responsible research conduct.

Francis L. Macrina
Richmond, Virginia
Assistance in preparing this updated edition came in many forms and from many people. An inventory of help included providing case studies or ideas for case studies, consultation and insightful conversations, manuscript review and editing, content ideas, provision of assorted instructional materials, and various and sundry assistance with manuscript production. For such contributions I thank: Wayne Barbee, Mark Bates, Lisa Ballance, John Blake, Alan Boehm, Al Chakrabarty, Amy Chuang, John Clore, Ponjola Coney, Daniel Conrad, Linda Costanzo, Richard Costanzo, Wu Deng, Janie Drinkard, Paul Fawcett, David Fenstermacher, Patty Gerber, Mary Jo Grap, Phil Hylemon, J. David Jentsch, Lindsay Kondo, Kenneth Kendler, Susan Kimbrough, Todd Kitten, Jane Lalich, Crystal Lantz, Joel Levine, Marston Linehan, Sahar Lotfi-Emran, Monika Markowitz, Charles McCarthy, Melissa McGinn, Ivelina Metcheva, Cindy Munro, Peter Nguyen, Ann Nichols-Casebolt, Susan Robb, Chet Scerra, Jessica Venable, Enid Virago, Stacy Voils, and James Ward. Special acknowledgement and thanks go to Michelle Stickler and Allen Morris who provided critical reviews and updating ideas for some of the chapters. I thank my colleague Andrekia Branch who, as usual, provided essential assistance in the production of the manuscript and the book’s companion website. Finally, I thankfully acknowledge Christine Charlip, Director, ASM Press, for her patience, guidance, and encouragement throughout this project. I am especially pleased to thank Ellie Tupper, Senior Production Editor at ASM Press, and to celebrate her expert contributions in the production of all four editions of Scientific Integrity.
Note to Students and Instructors

This text contains multiple means to facilitate learning by applying knowledge to solve problems or ethical challenges in the field of responsible conduct of research (RCR).

Each chapter contains discussion questions at the end of the textual material. These are designed for in-class discussion, or they may be used as the basis for writing assignments. Each question is open-ended and seeks to provoke thought based on what has been discussed in the body of the chapter.

Many of the topics covered in teaching scientific integrity lend themselves to the case study approach. Except for chapters 1 and 11, at the end of each chapter you will find 10 short cases designed for classroom discussion. These cases allow students to solve realistic problems encountered in scientific research, using their knowledge of responsible conduct issues coupled with their critical thinking skills.

Appendix I comprises a collection of brief surveys that probe attitudes and knowledge about core areas of RCR. These surveys may be used as instructional tools by having students in RCR courses complete them, followed by the presentation of the compiled results in class. This can be orchestrated by the instructor or the students. Presentation of such results, especially response patterns that show a difference of opinion on an issue, serves as a catalyst to promote classroom discussion with an eye toward exploring knowledge and attitudes about topic areas in research conduct.

Appendix II contains complex case-type scenarios that may be discussed in class or written about. Their complexity often demands some research to formulate solutions or answers to questions posed.

Appendix II also contains a dramatic script that provides an opportunity for students to role-play a scenario about authorship in science. It is
Note to Students and Instructors

designed for use with anywhere from a few to 11 students. Students are given scripted lines to recite and then must use ad lib presentation to make their case for (or against) authorship on a proposed manuscript.

How To Use End-of-Chapter Case Studies

The end-of-chapter short cases are designed for classroom use. These short scenarios are 200 to 400 words and can be read aloud in a few minutes. Most of the cases in this book have been used in our courses. Students are assigned two to three cases from which they select one to present for discussion to a small group of classmates.

Assigning a case set in advance of the class provides students with the opportunity to think about their arguments and to have time to do research or to seek consultation on the topic. For example, a student might want to consult relevant guideline or policy documents. Although many cases do not require research, they may not work as well if the student has not been at least indirectly exposed to the research environment. In the student evaluations of our courses, we have asked what factors were important in the selection of cases for discussion. Student responses indicate that two of the most important features are (i) the belief that the case would promote lively classroom discussion and (ii) the fact that the case had some personal appeal. That is, students frequently picked cases about which they had some background knowledge or personal experience.

A student leading the discussion of the case begins by reading it aloud in class. He or she then acts as the moderator for the rest of the discussion of the particular case. Discussion of cases is aided by a seating arrangement that allows everyone in the classroom to see one another (e.g., seating around a conference table or arranging chairs into a circle or semicircle). Typical classroom seating arrangements with students facing the front of the room make it difficult for everyone to see who’s talking, and this inconvenience can dampen group participation. Case discussions work optimally in small classrooms, with no more than 10 to 12 students. A typical case discussion will take 15 to 20 minutes.

Student participation is very important in the process. The instructor—who is present during the discussion—should serve only as a facilitator, contributing when clarification is needed, when discussion bogs down, or when closure on a case is needed. After reading the case, the student presents his or her impressions, identifying the issues and suggesting a possible solution. The classroom is then open to discussion, and the students air their views on the topic without more than one person talking at once. The instructor or student moderator may have to act as a peacekeeper. Sometimes disputes arise and discussions can become animated, even
intense. However, dialogue should never be allowed to become insulting or inappropriate or to include ad hominem comments.

Short cases are designed to encourage the discussants to think critically as they analyze and solve the problem at hand. For many cases, this will mean dissecting the facts of the case and separating the relevant issues from the non-relevant ones. Cases will evoke uncertainties and ambiguities. Sometimes the discussion will begin by students asking questions about the case. If something needs clarification or explanation, it should be provided by the student discussant or by the instructor, when needed. It is appropriate for the case leader to make assumptions about the scenario in order to keep discussion moving towards closure.

One of the principal features of the cases is that they allow discussants to apply their knowledge and personal standards to problems encountered in doing scientific research. Discussion should lead to one or more acceptable solutions to the problem. This is important to remember in bringing cases to closure. Much of the time a consensus answer will not emerge. There may be several acceptable solutions. In proposing solutions, discussants should always be able to arrive at a position that can be defended. A solution is valid as long as it is legal and does not violate what the discussants view as acceptable norms and standards, written or otherwise.

The case reader should evaluate the quality and quantity of the class discussion and bring the case to closure at the appropriate time. Summarizing the discussion helps to do this. Any opposing points of view should be adequately represented in the summary. Occasionally, there may be students who are uncomfortable with the outcomes reached. If this happens, the instructor should encourage continued discussion outside of the classroom with him or her, or with the student’s mentor.

In summary, case discussion should foster critical thinking as the discussants examine and apply their personal and professional values. The process is one of self-discovery as students formulate answers based on their values and knowledge of professional standards and practices.
This website, created and maintained by the author, may be accessed at: www.scientificintegrity.net

The site is arranged into sections that correspond to the textbook chapters. It features:

- All of the URLs cited in the text, allowing easy user access to online resources;
- URLs to supplemental materials in all of the chapter topic areas
- Updates on policies and regulations pertaining to research conduct and RCR education
- PDF files of each of the surveys contained in Appendix I, which can be printed for classroom use by students and instructors
- Short case discussions providing exemplars that will inform future case discussants about the scope and depth of the analysis of selected scenarios.

The website does not require user registration and is not password protected.