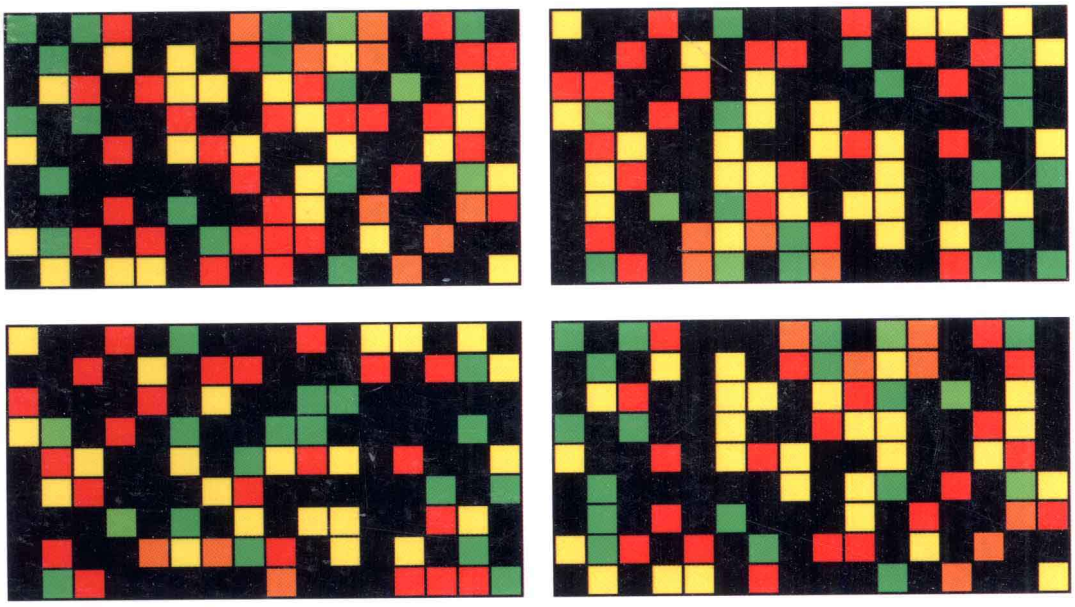
Scientific Integrity

AN INTRODUCTORY TEXT WITH CASES

SECOND EDITION



Francis L. Macrina

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SECOND EDITION

Francis L. Macrina

Professor and Director, Institute of Oral and Craniofacial Molecular Biology
Virginia Commonwealth University, Richmond, Virginia

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Publisher's Note

Scientific Integrity: an Introductory Text with Cases (Second Edition) is intended to serve as a text for courses and seminars 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.

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To Mary

For understanding, patience
And, most of all, love
Beyond our vows of 30 years ago

Contributors

S. Gaylen Bradley, Ph.D.
Vice President for Academic Affairs
University of Maryland Biotechnology Institute
Baltimore, Maryland
(Presently: Professor, Department of Humanities, Pennsylvania State University College of Medicine, Hershey, Pennsylvania)

Bruce A. Fuchs, Ph.D.
Director, Office of Science Education
National Institutes of Health
Bethesda, Maryland

Michael W. Kalichman, Ph.D.
Research Ethics Program Coordinator
Associate Professor of Pathology
University of California, San Diego
La Jolla, California

Thomas D. Mays, Ph.D., J.D.
Morrison and Foerster LLP
Washington, D.C.

Cindy L. Munro, Ph.D.
Associate Professor of Adult Health Nursing
Virginia Commonwealth University
Richmond, Virginia

Paul S. Swerdlow, M.D.
Professor of Medicine
Barbara Ann Karmanos Cancer Institute
Wayne State University
Detroit, Michigan

Foreword

MANY STUDENTS ARE DRAWN TO MODERN BIOLOGY and biomedical research by the challenge of solving complex intellectual problems and the opportunity to contribute to human knowledge and the improvement of public health. Training to achieve these goals is lengthy and arduous and requires not only an understanding of important biological and allied scientific principles, but a sense of the social, ethical, and legal context in which modern biology is practiced. Until recently, students received all of their training in these non-scientific disciplines through the words and actions of their mentors and through informal discussions with peers and other scientific colleagues. The enormous power of current biology to alter the world in which we live, and the increasing interest of the public in the activities of research biologists, has necessitated development of more formal training in the ethics, rules, regulations, and laws which govern the conduct of science.

This volume summarizes all of the important areas of scientific integrity and responsible conduct of science, including current ethical issues in modern biomedical research, conflicts of interest, issues related to authorship and collaboration, intellectual property issues and record keeping, and the use of both humans and animals in biomedical research. Following a brief description of the relevant facts, ethical issues, and legal and regulatory requirements, each chapter provides a series of case studies for classroom discussion. Two important principles are carefully followed in this volume: the information is presented in a manner which recognizes the controversial nature of many of the issues and balances opposing points of view, and the case studies are stimulating and likely to result in effective classroom discussions which will interest students in these subjects. Additional teaching

tools are found in the appendices, which include sample survey forms for gauging student opinion about a variety of topics associated with responsible conduct of science, some more detailed case studies, the Guidelines for the Conduct of Research at the National Institutes of Health, standard animal and human research protocols, and an example of a U.S. patent.

The target of this text is graduate-level students, but advanced undergraduates and postdoctoral students are also likely to benefit from the information and discussion of the case studies. More senior faculty should be encouraged to become more familiar with more recent information in the book and to participate fully in the case discussions. Although the information in this book is specifically targeted to academic environments, much of it will be useful to trainees and scientists in industry and government. In these cases, institution-specific rules also will apply, and the reader and discussants should be certain they are fully informed about the specific requirements of their organizations.

While it is not surprising that there are some statements in this volume about which well-informed, thoughtful scientists and members of the public will disagree, it is striking how much consensus has developed around some of the important ethical principles which guide the action of scientists in their daily work. Standards related to authorship, collaboration, sharing of research reagents, and mentorship are held commonly by the great majority of practicing scientists. The development of common ethical standards which guide scientific conduct speaks positively for the ability of scientists to acknowledge the important societal role that they play and to effectively oversee their own conduct.

Michael M. Gottesman, M.D.
Bethesda, Maryland
August, 1999

Preface

THIS TEXTBOOK AND ITS FIRST EDITION PREDECESSOR GREW from a course in Scientific Integrity I began at Virginia Commonwealth University in the mid-1980s. I was aided again by some of my teaching colleagues in writing the second edition. The book aims to provide a core of topic areas that can be used to teach trainees about the principles of scientific integrity. The content of the book is enhanced by the inclusion of interactive exercises like cases and surveys. We are convinced that the case study approach to scientific integrity is effective and worthwhile. It is rewarding for all involved. We instructors often find ourselves learning new things right along with our students as case discussions unfold and classroom participants apply personal knowledge and ethical standards to analyze and solve problems.

So what's new in the second edition? Every chapter of the first edition has been revised. Some have received important updating; others have undergone significant revision. Some of the end-of-chapter cases have been refined, and others have been dropped in favor of more timely and topical ones. New cases have been added: across the whole text, more than 50% of the short cases are new. Two new chapters have been written for this edition, one on ethical principles and the scientist and one on collaborative research. The class survey material has been significantly expanded and revised. Useful appendix material which augments some of the topic areas has been added. New appendixes include a U.S. patent with narrative, human and animal use protocols, and a verbatim example of an institutional standards-of-conduct policy. Finally, the advances and availability of the Internet have had an impact. Each chapter now has a resources section noting the location of on-line information to augment the text's subject matter.

The Internet has also had an impact on how we teach our course at VCU. Along with this book, we now use a Web-based syllabus for our course. The Web site will provide information on course timing and logistics, semester writing assignments, and, in general, how we use our text in teaching scientific integrity. The URL for the course is

http://views.vcu.edu/~macrina/

This book is aimed at graduate and postgraduate trainees in the biomedical and natural sciences. It also will be useful to individuals who train or practice in related scientific fields. Although the subject matter of scientific integrity may be taught at different academic levels, our text is geared for graduate biomedical trainees, preferably those who have had some exposure to the graduate research laboratory. Usually, this means students who are at least beginning the second year of graduate study. There is a culture, language, and mind set that accompanies life in the research laboratory which is not revealed in the classroom setting. We believe that prior laboratory exposure greatly facilitates teaching the principles of scientific integrity. Most important, it gives the students a basis for identifying with the cases. Nonetheless, I have successfully used the first edition of *Scientific Integrity* as a text for teaching advanced undergraduates (with little or no laboratory experience), and I anticipate that the second edition will also be useful for teaching at that level.

In short, this is a book that covers a variety of topics related to the conduct of scientific investigation. But it is *not* a rulebook for the scientist. We discuss guidelines and policies, standards, and codes because we want our readers to be aware that many of these issues are influenced by both written policies and normative standards. We also talk about some of the acceptable ways to do things. Yet, the values of the individual scientist take on major importance in doing scientific research. This will become readily apparent in any case discussion session. 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. There are many acceptable possibilities.

We want to plant the seeds of awareness of existing, changing, and emerging standards in scientific conduct. Applying critical thinking in using the information we present about standards and other normative behavior is equally important. Lifelong learning is as much a part of scientific integrity as it is of any rigorous scientific discipline.

Francis L. Macrina
Richmond, Virginia

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My family provided enormous support and inspiration during this book-writing project, and I thank them and love them for that.

F. L. M.

Notes to Students and Instructors

MANY OF THE TOPICS COVERED IN TEACHING scientific integrity lend themselves to the case study approach. Except for chapters 1 and 2, at the end of each chapter you will find cases for classroom discussion. Additional examples of case studies in responsible scientific conduct may be found in the books listed at the end of this note.

How To Use End-of-Chapter Case Studies

This book contains two types of cases. The end-of-chapter short cases are designed for classroom use. Extended cases that lend themselves to a written response are contained in Appendix II. The short cases 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 course. We assign sets of cases (e.g., from a single chapter) to small groups of two or three students, asking them to choose cases to present. Students then individually present their selected cases in the designated class session. 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 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 exposed to a graduate research environment. In the student evaluation of our course, we regularly ask 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 15 to 20 students. Smaller is even better. A typical case discussion will take 15 to 20 minutes.

Student participation is very important in the process. The instructor should serve only as a facilitator, contributing when clarification is needed, when discussion bogs down, or when closure on a case is needed. The student reads the case and 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. If the dialogue becomes emotional, insulting or inappropriate comments should not be allowed. Ad hominem comments are unacceptable, and discussants should be cautioned against their use.

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 nonrelevant 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.

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 same 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 "right answers," all of which are acceptable. There will always be clear "wrong answers." In proposing solutions, discussants should always be able to arrive at a position that can be defended. Answers may be ranked by merit as part of the case discussion, but usually this is not necessary. 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. The application of relevant guidelines, codes, and policies should be brought into play. One final note on case resolution. We have deliberately omitted discussing the possible "answers" to the cases. Cases often have multiple acceptable solutions. Hashing over multiple acceptable answers runs the risk of assigning specific values to the various possibilities, which we feel is not desirable. Further, we believe that "wrong answers" will be obvious. In short, the process of solving the case studies is key to learning from them.

A few cases that are only modestly challenging have been placed at the beginning of each set of chapter cases. Using these cases to get started is recommended. They are designed to acquaint the student and the instructor with the process of case discussion and resolution using examples which lack the complexity of later cases in the set.

Extended Case Studies and Surveys

A different style of case study is longer and usually describes a more complex scenario. The required response is usually guided by specific questions or by a request to complete a written exercise. We call this format the extended case. A number of extended cases appear in Appendix II and explore some of our chapter topics. We have successfully used these extended cases to form the basis of a writing assignment for our course. Students have been required to select cases and write a response of one to two typewritten single-spaced pages per case. In effect, this becomes a term paper upon which part of the course grade is based.

Appendix I contains some surveys which we have found to be useful teaching tools. As with the short cases, we assign these surveys to small groups of students (usually two) on the first day of class. The students collect the completed response sheets from their classmates on an assigned date, collate the data, and present an analysis of the results. Printed response sheets corresponding to each survey are provided by the instructor. Response sheets are submitted anonymously. The assignment includes the date by which the rest of the class must turn in their responses to the students conducting the survey. A date on which the results of the survey will be discussed in class is also set. The student survey-takers then collate the

data and prepare a handout or overhead transparency for class presentation of the results. Class time is reserved during a relevant session for discussion of the survey results. This discussion is led by the student survey-takers, and class participation is encouraged. For example, responses to questions that displayed considerable disparity can be explored. A more detailed explanation of the use of surveys as a teaching tool is presented in Appendix I. We have found that these exercises provide some of the same benefits as the short case discussions. Class discussion of survey results can be lively as students come to recognize and appreciate differing points of view on issues related to scientific conduct and training.

Resources

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