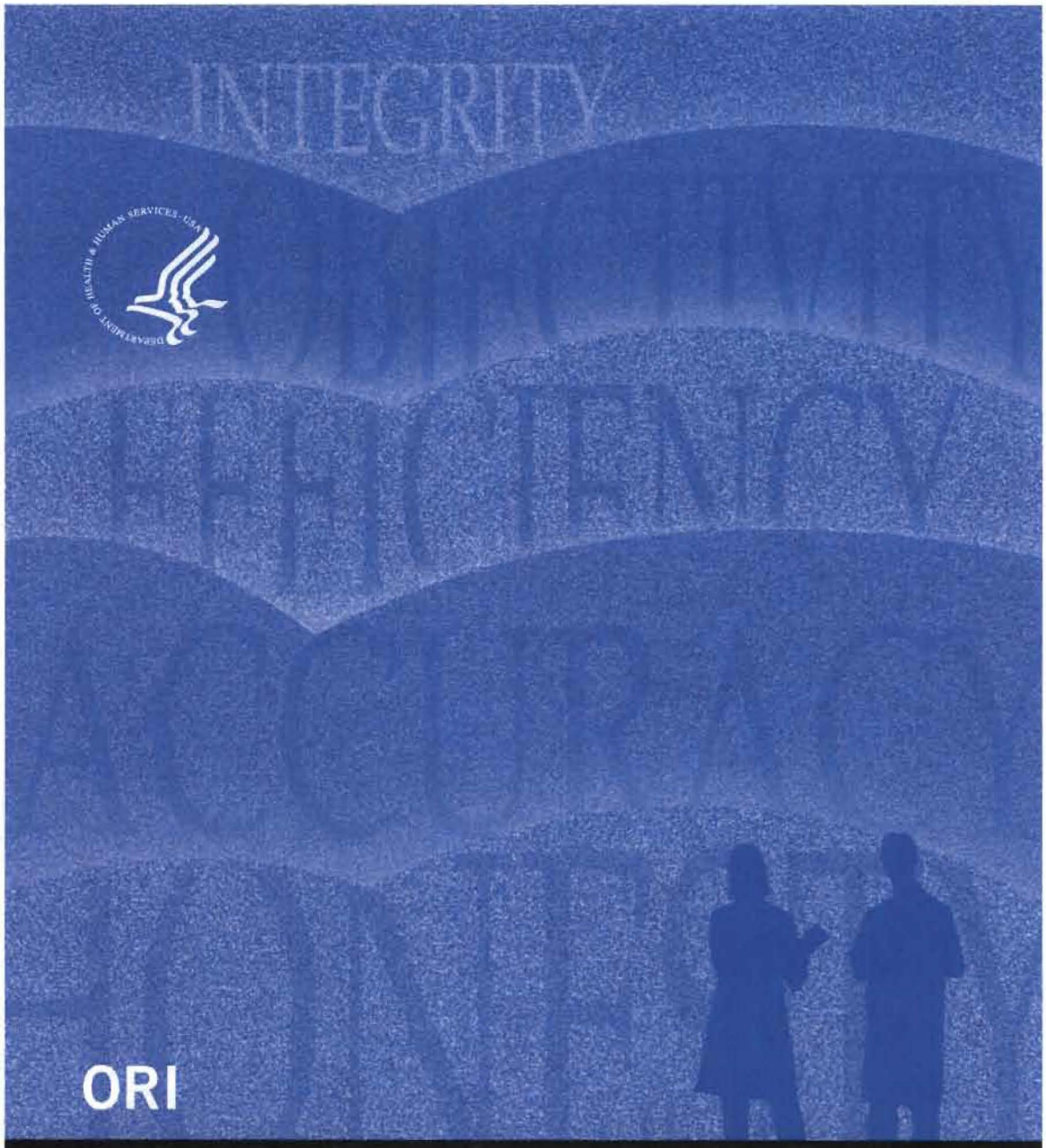

Introduction to the Responsible Conduct of Research

Nicholas H. Steneck

illustrations by David Zinn

ORI

Introduction to the Responsible Conduct of Research

Nicholas H. Steneck
illustrations by David Zinn

Revised Edition
August 2007

Setting off on the road to the responsible conduct of research

Frontis Material

Foreword

The Office of Research Integrity (ORI) oversees and directs Public Health Serv-ice (PHS) research integrity activities on behalf of the Secretary of Health and Human Services and the American public. This responsibility extends to around $30 billion in Federal research support, devoted primarily to the biomedical and behavioral sciences through intramural and extramural programs, and to the thousands of researchers, research staff, and research administrators who work on PHS-funded research.

As part of its efforts to promote integrity in PHS-funded research, ORI isauthorized to undertake activities and to support programs that enhance education in the responsible conduct of research (RCR). The ORI Introduction to the -Responsible Conduct of Research is being issued to further this important mission.

The importance of formal RCR education was first explicitly recognized in the 1989 Institute of Medicine Report, The Responsible Conduct of Research in the Health Sciences, and has since been endorsed by other groups and members of the research community. Thanks to this support, researchers who want to learn about or help others understand responsible conduct in research have many resources available, from formal courses to web-based instruction programs, a growing array of challenging books, and the experience of established researchers conveyed through mentoring.

The ORI Introduction to RCR seeks to supplement existing resources by makinga comprehensive overview of basic rules of the road for responsible researchavailable to all PHS-funded researchers. It has been prepared with the needs of small and mid-size research institutions and beginning researchers in mind, since we have often been asked to provide resources for this community, but it may find use in other settings.

In issuing this publication, it needs to be stressed that ORI is not establishing or even recommending how RCR ought to be taught. We understand that responsible conduct in research can be and is learned in different ways, that the standards for responsible conduct can vary from field to field, and that in many situations two or more responses to a question about responsible research may be considered acceptable research practice. We hope the ORI Introduction to RCR will therefore be seen as the beginning and not the end of learning about this important aspect of professional life.

Chris B. Pascal, J.D.
Director
Office of Research Integrity

Top Table of Contents ORI Homepage

Frontis Material

Preface

Spurred by a growing belief in the importance of science and technology, public support for research increased dramatically over the course of the 20th century. A century ago, research did not play a major role in the average person's life. Today, few aspects of life are not touched in one way or another by the information and technologies generated through research.

With growing public support for research has come an understandableconcern about the way it is conducted. Public funds support roughly one-third of all research and development (R&D) in the U.S. and half of all basic research. Many researchers, therefore, spend a significant portion of their time working for the public. As public servants and also professionals, researchers have clear obligations to conduct their research in a responsible manner.

In general terms, responsible conduct in research is simply good citizenship applied to professional life.

In general terms, responsible conduct in research is simply good citizenship applied to professional life. Researchers who report their work honestly, accurately, efficiently, and objectively are on the right road when it comes to responsible conduct. Anyone who is dishonest, knowingly reports inaccurate results, wastes funds, or allows personal bias to influence scientific findings is not.

However, the specifics of good citizenship in research can be a challenge to understand and put into practice. Research is not an organized profession in the same way as law or medicine. Researchers learn best practices in a number of ways and in different settings. The norms for responsible conduct can vary from field to field. Add to this the growing body of local, state, and Federal regulations and you have a situation that can test the professional savvy of any researcher.

Researchers learn best practices in a number of ways and in different settings. The norms for responsible conduct can vary from field to field.

The ORI Introduction to the Responsible Conduct of Research has been written primarily for researchers and research staff engaged in research supported by the Public Health Service but is applicable to scholarly research in general. As an "introduction," it seeks to provide a practical overview of the rules, regulations, and professional practices that define the responsible conduct of research. The coverage is not exhaustive and leaves room for continued reading and discussion in the laboratory and classroom, at professional meetings, and in any other setting where researchers gather to discuss their work.

The content is organized around two ways of thinking about research. The main sections follow the normal flow of research, from a consideration of shared values to planning, conducting, reporting, and reviewing. The chapters within the main sections cover nine core instructional areas that have been widely recognized as central to the responsible conduct of research. An opening chapter on rules of the road and a brief epilogue on responsible research round out the coverage.

Although designed to follow the normal flow of research, the chapters in this volume are all more-or-less self-contained and can be read in any order. Each opens with a **short case** in which students and researchers are faced with making decisions about the responsible conduct of research. Throughout the chapters, important points are summarized in **bulleted lists**. Each chapter ends with a set of closing **questions** for further discussion and **resources** for reference and additional reading. The Web addresses given for the resources and elsewhere in this work were current at the time of printing.

While written with all researchers in mind, special consideration has been given to the needs of students, postdocs, and researchers who do not have easy access to responsible conduct of research materials or to colleagues who can explain the intricacies of responsible conduct in research to them. Two or three hours with this book should provide anyone in this position with a better understanding of the reasons for and the scope of the most important responsibilities researchers have.

Many colleagues have generously provided comments on parts or all of this work as it took shape over several drafts, including Ruth Bulger, Tony Demsey, Carolyn Fassi, Peggy Fischer, Mark Frankel, Nelson Garnett, Shirley Hicks, Erich Jensen, Mike Kalichman and his students, Nell Kriesberg, John Krueger, Tony Mazzaschi, Judy Nowack, Chris Pascal, Ken Pimple, Larry Rhoades, Fran Sanden, Mary Scheetz, Joan Schwartz, David Shore, Peggy Sundermeyer, and Carol Wigglesworth. Co-creator, artist David Zinn, patiently produced multiple versions of his drawings as we worked together to turn serious dilemmas into lighter but thought-provoking illustrations. ORI Director, Chris Pascal, and Associate Director, Larry Rhoades, deserve credit for initiating and carrying through on this project. If through promoting integrity and responsible conduct in research this work helps preserve the place of research in society today, it will have been a project well worth undertaking.

Nicholas H. Steneck
Ann Arbor, MI

Top Table of Contents **ORI Homepage**

1. Rules of the Road

Introduction

How should you conduct your research? What practices should you follow? The public and their professional colleagues expect researchers to follow many rules and commonly accepted practices as they go about their work advancing knowledge and putting knowledge to work. Responsible conduct in research is conduct that meets this expectation.

Setting off on the road to the responsible conduct of research (enlarge)

Short Case

Society's expectations for the responsible conduct of research are complex and not always well defined. Becoming a responsible researcher is not like becoming a responsible driver. Responsible driving is clearly defined through laws and written down in drivers' manuals. Before individuals are allowed to drive, they are tested on both their knowledge of the rules of the road and their skills. Then, licensed drivers are constantly reminded of their responsibilities by signs, traffic signals, and road markings. They also know that their behavior as drivers is monitored and that there are specific penalties for improper behavior.

Guidance for the responsible conduct of research is not this well organized. Some responsible practices are defined through law and institutional policies that must be followed. Others are set out in non-binding codes and guidelines that should be followed. Still other responsible practices are commonly accepted by most researchers but not written down. Instead, they are transmitted informally through mentoring, based on the understandings and values of each mentor. This situation is further complicated by the fact that researchers are not routinely tested on their knowledge of responsible practices or licensed. Moreover, their behavior as researchers is inconsistently monitored and the penalties for irresponsible behavior vary considerably.

Researchers do, of course, care deeply about responsible behavior in research and pay a great deal of attention to best research practices. The fact remains, however, that it can take some effort to find out what these practices are and how to act when the complex rules for responsible practice seem to conflict with one another.

This chapter describes the four basic sources of rules of the road for the responsible conduct of research:

- professional codes,
- government regulations,
- institutional policies, and
- personal convictions.

If you are primarily interested in learning more about your responsibilities rather than understanding their origin, skip ahead to the substantive chapters that follow, returning to this chapter later, when it might have more relevance.

Top Table of Contents ORI Homepage

1. Rules of the Road

1a. Professional self-regulation

Prior to World War II, society provided little public support for research and did not expect much from researchers in return. Researchers were more or less left alone to run their own affairs, except when they assumed other roles, as teachers, physicians, or engineers.

NAS
On Being a Scientist

As professionals, researchers have not been particularly concerned about rules for self-regulation. Since the goal of research is to advance knowledge through critical inquiry and scientific experimentation, it has commonly been assumed that the normal checking that goes on in testing new ideas is sufficient to keep researchers honest. Based on this assumption, research arguably does not need specific rules for self-regulation because it is, by definition, an activity that routinely monitors itself.

American Chemical Society
Chemist's Code of Conduct

The lack of a perceived need for specific rules poses problems for researchers who want guidance on responsible research practices. Intellectually and professionally researchers organize their lives around fields of study. They are biologists, chemists, and physicists, increasingly working in specialized areas, such as biophysics, biochemistry, molecular biology, and so on. However, the societies that represent fields of study for the most part have not developed comprehensive guidelines for responsible research practices. Many do have codes of ethics, but most codes of ethics are simply general statements about ideals and do not contain the specific guidance researchers need to work responsibly in complex research settings.

Fortunately, there are a few important exceptions to this last generalization. Comprehensive descriptions of responsible research practices can be found in (see the resources listed at the end of this chapter for references):

- reports and policy statements issued by the National Academy of Sciences, the American Association for the Advancement of Science, the Association of American Medical Colleges, and Sigma Xi;
- guidance on responsible publication practices published in journals; and
- a few comprehensive professional codes.

When applicable, the guidance provided by professional societies is a good place to begin learning about responsible research practices.

Top Table of Contents ORI Homepage

1. Rules of the Road

1b. Government regulation

NIH Training Requirement

As public support for research grew after World War II, the public, through its elected officials, became more interested in the way research is practiced. Over time, concerns began to surface about some of these practices, focusing initially on the use of animals and humans in research and later on research misconduct. When it appeared that the research community was not doing enough to address these concerns, government turned to regulation.

Government regulations usually begin in Congress. When a potential problem is identified, Congress calls hearings to learn more about the problem and then passes legislation to fix it. The regulations covering the use of humans and animals in research as well as research misconduct stem from three acts passed by Congress:

- the 1966 Animal Welfare Act (PL 89-544),
- the 1974 National Research Act (PL 93-348), and
- the 1985 Health Research Extension Act (PL 99-158).

These and other research-related acts give the Federal Government the authority to regulate the research it funds.

Along with the authority to address problems, Congress usually provides guidance on general objectives, but it seldom drafts detailed regulations. This job falls to the Federal agencies in the Executive Branch of government, which are responsible for carrying out the law. Federal agencies translate Congressional directives into regulations (also called rules), policies, and guidelines.

In 1989, the Department of Health and Human Services (HHS) established the Office of Scientific Integrity (OSI) and the Office of Scientific Integrity Review (OSIR), in response to the 1985 Health Research Extension Act. The Office of Research Integrity (ORI) was established in 1992 and assumed the responsibilities previously assigned to OSI and OSIR. In addition to responding to misconduct, ORI undertook a number of steps to promote integrity and responsible research practices. The ORI Introduction to RCR is a result of that effort.

Regulations. When Federal agencies translate Congressional directives into regulations, they must follow provisions set out in the Federal Administrative Procedure Act (5 USC 551-702). As its name implies, this act establishes procedures for developing new regulations, including steps for getting public input. Before establishing a new regulation, an agency must issue a draft regulation, obtain and consider public comment, and then issue the final regulation. Each step must be published in the Federal Register–the "official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents" (link). Objections raised during the public comment period must be addressed before the final regulation is adopted. After it is adopted, the final regulation is incorporated into the Code of Federal Regulations and becomes official government regulatory policy that must be followed.

Agency policies and guidelines. Executive Branch agencies have the authority to issue some policies as part of their normal operation. The National Institutes of Health (NIH), for example, has the authority to establish policies for grant awards. From time to time, it changes these policies to assure that its research funds are spent wisely and responsibly. It is in this capacity that NIH issued a special RCR "Training Grant Requirement" in 1989 and the more recent "Required Education in the Protection of Human

Research Participants" (discussed in Chapter 3).
Federal agencies also issue Guidelines, which recommend but do not require a particular course of action. To help research institutions handle allegations of research misconduct (see Chapter 2), ORI issued as guidelines a Model Policy and Procedures for Responding to Allegations of Scientific Misconduct (link). In this case, the model policy is intended to provide guidance and does not impose binding requirements on institutions.

The plethora of Federal regulations, policies, and guidelines that affect research can be confusing. They do not always speak with one voice. The same aspect of a research project can be subject to regulations by more than one Federal agency, as for example the use of human or animal subjects. Common Federal regulations, such as the Federal Policy on Research Misconduct (discussed in Chapter 2) and the "Common Rule" for human subjects research (discussed in Chapter 3), are not truly common regulations until they have been adopted by all agencies. In addition, distinctions between regulations, policies, requirements, guidelines, and recommended practices can be difficult to understand.

Researchers are well advised to seek help when it comes to understanding Federal and state research regulations. The Federal agencies that regulate research have comprehensive Web pages that list and explain their policies and regulations and readily answer questions. For local advice, your institutional research administrators may be the best place to begin.

Top Table of Contents **ORI Homepage**

1. Rules of the Road

1c. Institutional policies

Research institutions (universities, hospitals, private research companies, and so on) are required by law to have policies that cover various aspects of their research programs if they accept Federal funds. They must have committees to review human and animal research (discussed in Chapter 3 and Chapter 4). They must have procedures for investigating and reporting research misconduct (Chapter 2) and conflicts of interest (Chapter 5). They must approve and manage all research budgets, ensure that laboratory safety rules are followed, and follow established practices for the responsible use of hazardous substances in research. They must also provide training for researchers who use animal or human subjects in their research and for individuals supported on NIH training grants.

Stanford Research Policy Handbook

To help manage their responsibilities, most research institutions have research offices/officers and institutional research policies. Both provide excellent sources of guidance for responsible conduct in research, since both are the products of the institution's efforts to clarify its own responsibilities. In addition, institutional policies are often more comprehensive than Federal and state policies since they must encompass the full panoply of institutional responsibilities. So, for example, many research institutions have more comprehensive definitions of research misconduct than the Federal Government to cover other practices that can undermine the integrity of research, such as the deliberate violation of research regulations, abuses of confidentiality, and even the failure to report misconduct (discussed in Chapter 2). Most also require institutional review for more human subjects research than is required by Federal regulation.

Large research institutions usually have Web sites that contain some or all of the following information:

- copies of institutional research policies,
- links to state and Federal policies,
- required forms and instructions for completing them,
- responsible conduct of research training programs, and
- lists of key personnel.

here is, of course, little or no coordination across different research institutions, so the information on an institution's Web site pertains only to that institution. But if you are looking for a comprehensive set of rules of the road for responsible research, check your home institution's research administration Web site or one from a comparable institution.

Top Table of Contents ORI Homepage

1. Rules of the Road

1d. Personal responsibility

As important as rules of the road are for the responsible conduct of research, they have two important limitations.

First, rules generally set minimum standards for behavior rather than strive for the ideal. The rules say that you can drive at 65 miles per hour over a stretch of road, but there may be times or circumstances when 55 would be better. If you use human subjects in research, you must follow specific rules, but there may be situations in which you should strive for a higher standard of conduct. Responsible research requires more than simply following rules.

Second, rules will not resolve some of the personal conflicts and moral dilemmas that arise in research. Journals have rules against listing undeserving authors on papers (individuals who have not made significant contributions to the research described in the paper). These same rules do not tell you what to do if the undeserving author can have a significant influence on your career. Rules also cannot replace the critical reasoning skills needed to assess ethically controversial human or animal experiments or conflicts of interest. Researchers will face ethical dilemmas in research. They should be able to recognize these dilemmas and know how to resolve them (discussed in Chapter 11).

The rules of the road for research therefore need to be supplemented with good judgment and a strong sense of personal integrity. When meeting deadlines, you can cut corners by filling in a few missing data points without actually running the experiments or adding a few references to your notes that you have not read. You can resist sharing data with colleagues or leave some information on method out of a publication to slow down the competition. You can ignore your responsibilities to students or a mentor in order to get your own work done. You can do all of these things and more, but should you?

In the final analysis, whatever decision you make when you confront a difficult decision about responsibility in research, you are the one who has to live with the consequences of that decision. If you are uncertain whether a particular course of action is responsible, subject it to one simple test. Imagine what you are preparing to do will be reported the next day on the front page of your local newspaper. If you are comfortable having colleagues, friends, and family know what you did, chances are you acted responsibly, provided, of course, you also understand your responsibilities as a researcher, as described in the rules of the road covered in the rest of the ORI Introduction to RCR.

Top Table of Contents ORI Homepage