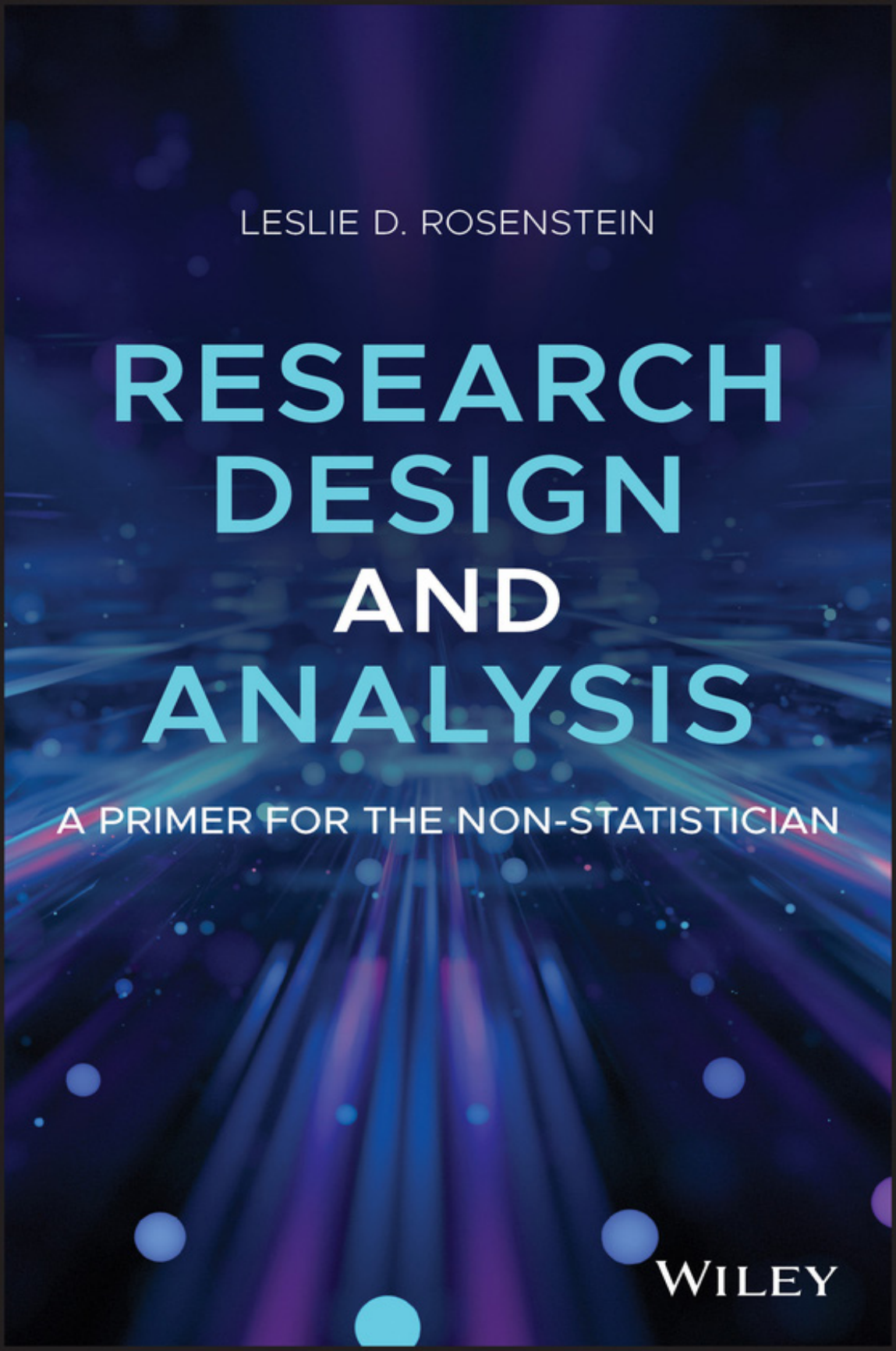
LESLIE D. ROSENSTEIN
RESEARCH DESIGN AND ANALYSIS
A PRIMER FOR THE NON-STATISTICIAN
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Research Design and Analysis

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A Primer for the Non-Statistician

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I am grateful for my loving and supportive family who has helped me overcome some hefty obstacles. I would not have been able to write this book without the support of Jean, Marv, Dana, Shari, Kevin, Cory, and Caleigh.

I also want to acknowledge my students at UT Southwestern Medical Center for their patience and interest. Their reactions during class discussions, though hard to read at times, helped guide me in organizing and formulating the chapters of this primer. I especially want to thank Dr. Mallory Jacobs who inspired me to try to write something succinct and user-friendly for busy physicians who want to be good consumers of clinical research.

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Introduction

In this book, I set out to provide a hopefully, pain-free overview of research methods, design, and analysis. The intended audiences include those in the sciences who wish to conduct their own research without investing several semesters completing coursework in statistics and related fields, as well as those in the sciences, clinical fields, education, and the media who wish to read published research in an informed manner. In the former case, this manuscript will provide a general basis for designing and conducting research, though with the assistance of a statistical consultant. In the latter case, I hope this primer will provide a basis for reading, understanding, and critically evaluating research reports.

For health care providers who wish to read studies and make treatment recommendations to their patients based on study outcomes, I hope this book will be a good reference tool. Research publications can sometimes be full of nuances and jargon that are only meaningful to the trained researcher. Without a clear understanding of research design, validity, and interpretation, the results reported in publications can be misunderstood and applied improperly. Sometimes, the research may be poorly conducted or poorly reported, and a basic knowledge of research design and interpretation can be particularly useful in judging when that is the case. At other times, the research is well done, but difficult to understand without a basic knowledge of research methods.

Professionals working in the media are well aware of their great responsibility in reporting research findings to the public. The media has a special role in providing information to the public while avoiding harm as outlined in the *Professional Journalists' Code of Ethics* (Society of Professional Journalists, 2014). That code also mandates that journalists are responsible for the accuracy of their reporting, including verifying the information before it is released.

Carrie Figdor (2017) points out the difficulty presented to journalists in their role of reporting and providing information that is accurate when the material is the product of scientific endeavors. Journalists cannot necessarily rely on authors of scientific reports to provide accurate and valid information, and this quandary has become exponentially worse with the evolution of mass

communication tools. Non-peer-reviewed research reports are more readily available to the masses. Moreover, journalists cannot necessarily count on peer-reviewed journals to publish only sound research. Most do, but journalists must be careful, yet, to review and understand the research design as presented along with the results and conclusions.

Journalists must take care, for instance, to not translate a conclusion of an association between two events or variables into a claim of causality. Oftentimes, the correct language to that effect is included in a research publication, but it is incumbent on the journalist to read and understand such language. Otherwise, there is a real and great risk that the public will be misinformed and harmed as a result. In Chapter 9, I discuss this in more detail with respect to specific instances of marked harm being perpetrated unintentionally (e.g. the unsubstantiated fear of the measles vaccine, misinformation about the true risks of chronic traumatic encephalopathy, and misinterpretation of the Women's Health Initiative findings).

The chapters of this book are laid out into four major sections. In Section 1, I briefly review the purpose of research as well as ethics and rules guiding research involving human participants and animal subjects. In Section 2, I walk you through basic research designs and validity. In Section 3, I provide a cursory review of statistical techniques, just enough to make you conversant with your statistical consultant or to be able to comprehend the jargon you find in many research documents. I have also included a chapter on meta-analytic studies. The goal of that chapter is to help you in sifting through reports of meta-analyses, though I also provide some direction in case you ever consider conducting your own meta-analytic study. In the fourth section, I review the how-tos of disseminating research findings, including reporting and presenting research results. I discuss how to prepare a research paper for submission to a peer-reviewed journal. I also talk about the concept of poster presentations and how to submit research more quickly for presentation at a conference.

In Section 4, I also present my concluding remarks. There, I repeat what I emphasize throughout this primer; that is, research and research findings are only as good as the research design. Most importantly, it is crucial to avoid making statements of claims of causality between two conditions, or variables, when the research design does not permit drawing such conclusions with any degree of confidence. Accurate interpretation of research findings is of critical importance. This does not just apply to the authors of the original research but also to others who report about and share research findings and claims more broadly. In particular, I hope to underline the importance and responsibility carried by journalists and others who discuss research claims. Sadly, when research claims are reported and shared with the public without a critical eye or with misstatements about causality, harm may ensue.

Finally, I have prepared appendices with tools for those who are planning to conduct their own research. These contain information about data sets, databases, statistical software programs, and resources for those who want to learn more about inferential statistics. I have additionally included a glossary of many of the terms included in this primer; in the glossary, terms are alphabetized for quick lookup.

Section 1

The Purpose, Ethics, and Rules of Research

1

The Purpose and Ethics of Research

1.1 The Purpose and Risks of Research

Why do we do research? There are many reasons: to answer a question, to advance understanding of a topic, to evaluate interventions, to predict behavior, to understand differences between groups, and so forth. When we conduct research, we usually start with an inquiry based on theory. We then develop hypotheses. Hypotheses are testable questions or predictions, which are ideally based on theory or pre-existing knowledge about a topic.

Is there ever a time when research should not be conducted? Yes! Logistically, some research ideas may not have benefits that outweigh the costs of conducting the research. These cost considerations include fiscal costs, time, and effort. But there are also ethical considerations in determining *whether* research should be conducted and *how* it is conducted.

In terms of the *whether*, one might ask if there are any potential harms of the research. Consideration of the issue of potential harm typically refers to the harm that may be incurred by the participants or subjects in the process of conducting the research, but harm can also theoretically result from the findings or the knowledge gained by the research. For instance, what if you want to know whether a necessary, life-saving treatment causes long-term cognitive impairments? One might argue that there is no point in "proving" the adverse effects of the treatment if the treatment is required for survival and there are no alternative options. On the other hand, perhaps patients deserve to be fully informed of the potential side effects before deciding whether to pursue treatment versus opting for fate. Perhaps, too, an understanding of negative side effects could lead to the development of strategies and interventions to minimize or reverse them.

As another example, many researchers may be interested in knowing the negative consequences of a certain type and severity of injury. If one stops there in the research, that is, if the research concludes following documentation of the negative impacts of an event or injury, then the research has

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