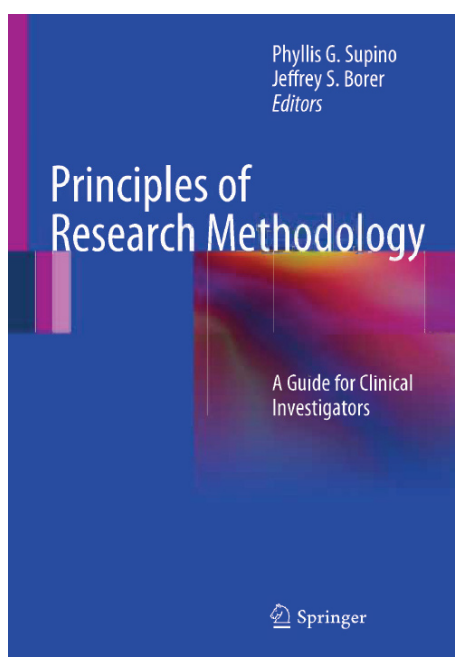


# Principles of Research Methodology A Guide for Clinical Investigators

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Written and edited by Dr. Phyllis Supino and Jeffrey Borer, this book on research methodology draws from the common experiences of those involved in training early-career researchers. Dr. Supino and Bohrer's book represents the collaboration of an accomplished educator and scholar with expertise in research methodology. The institute, of which Dr. Bohrer is director, is now located at the State University of New York Downstate Medical Center. Working as part of a research institute housed in a medical school, Dr. Borer soon discovered that many of the students in his program had no formal research training and little knowledge of research methodology. That is why he had the idea to write a book. The book includes in-depth chapters that not only generate research questions, but also provide important information on how to create better research, including researching a variety of databases, research grants, and documenting. On the history of the application of ethics to medical research. There also is a valuable chapter on statistical considerations and a fascinating discussion on the origins and elements of hypothesis generation. The book spans the entire research process, beginning with the conception of the research problem to publication of findings. This book consists of 13 chapters. A brief summary of the contents of each chapter. Chapter 1 describes the general characteristics of research and differentiates among various types of research; it also summarizes the steps typically utilized in the hypothesis-testing (hypothetico-deductive) method and underscores the importance of proper planning. Chapter 2 reviews the origins of clinical research problems and the types of questions that are commonly asked in clinical investigations; it also identifies the characteristics of well-conceived research problems and explains the role of the literature search in research problem development. Chapter 3 introduces the reader to various modes of logical inference utilized for hypothesis generation, describes the characteristics of well-designed research hypotheses, distinguishes among various types of hypotheses, and provides guidelines for constructing them. Chapter 4 takes the reader through classic epidemiological (observational) methods, including cohort, case-control, and cross-sectional designs, and describes their respective advantages and limitations. Chapter 5 discusses the meaning of internal and external validity in the context of studies that aim to examine the effects of purposively applied interventions, identifies the most important sources of bias in these types of studies, and presents a

variety of alternative study designs that can be used to evaluate interventions, together with their respective strengths and weaknesses for controlling each of the identified biases. Chapter 6 defines and describes the purpose of the clinical trial and provides in-depth guidelines for writing the clinical protocol that governs its conduct. Chapter 7 describes methodologies used for data capture and management in clinical trials and reviews associated regulatory requirements. Chapter 8 explains the steps involved in designing, implementing, and evaluating questionnaires and interviews that seek to obtain self-reported information. Chapter 9 reviews the pros and cons of systematic reviews and meta-analyses for generating secondary data by synthesizing evidence from previously conducted studies, and discusses methods for locating, evaluating, and writing them. Chapter 10 describes the various methods by which subjects can be sampled and the implications of these methods for drawing conclusions from clinical research findings. Chapter 11 introduces the reader to fundamental statistical principles used in biomedical research and describes the basis of determination of sample size and definition of statistical power. Chapter 12 describes the ethical basis of human subjects research, identifies areas of greatest concern to institutional review boards, and outlines the basic responsibilities of investigators towards their subjects. Finally, Chapter 13 provides practical guidance on how to write a publishable scientific paper. This time, we have selected the 2nd chapter from them and clarified the content and compiled it briefly. One of the most difficult aspects

of the research process is developing a research idea in the first place. The most common source of problems in clinical research is the myriad of practical issues that clinicians face in managing patients and must make data-driven decisions. Most well-designed manuscripts document the limitations of the investigation (eg, potential selection bias, insufficient sample size, low number of endpoint events, loss to follow-up) and may suggest directions for future research. Research problems may be proposed by public or private funding agencies that publish requests for proposals (RFPs) or applications (RFAs) to address understudied areas affecting public health. Solving a clinical research problem is considered important if it sheds light on an important issue affecting public health and ultimately leads clinicians (or health policy makers) to make decisions and take action. If the problem was not solved, it was not done, it was not done. If the research is extensive, it is recommended that the researcher divides the main problem into sub-problems, each of which deals with one problem. It is important that the sum of the content included in the sub-problems is not more or less equal to the amount of content included in the main problem. We think this book is a good work for researchers to understand because it explains the models commonly used in health research with examples. In addition, if this book is translated and used in Mongolia, it will be very useful for graduate students. The main reason is that there are few research books in this field in our country, so it can be used as a basic textbook.