

# Contents

<i>Contributors</i> .....	ix
<i>Foreword</i> .....	xiii
<i>Preface</i> .....	xv

## SECTION I: EVOLUTION OF CLINICAL RESEARCH

*Renato D. Lopes, editor*

### CHAPTER ONE

<b>A Brief History of Clinical Trials, Drug Regulations, and the Food and Drug Administration</b> .....	3
---	---

*Nidhi Tripathi, Kate Davis, Catherine Bodine, and Daniel K. Benjamin Jr.*

### CHAPTER TWO

<b>Information Technology, Access, ClinicalTrials.gov</b> .....	17
---	----

*Anjan K. Chakrabarti and C. Michael Gibson*

### CHAPTER THREE

<b>The Role of Academic Research Organizations in Clinical Research</b> .....	27
---	----

*Craig J. Reist, Tyrus L. Rorick, Lisa G. Berdan, and Renato D. Lopes*

### CHAPTER FOUR

<b>Ethics of Clinical Research: An Overview and Emerging Issues</b> .....	39
---	----

*Yee Weng Wong and Kevin A. Schulman*

**SECTION II: PRINCIPLES OF CLINICAL EXPERIMENTATION**

*Daniel K. Benjamin Jr. and Karen S. Pieper, editors*

CHAPTER FIVE

<b>Introduction to Clinical Experimentation .....</b>	<b>65</b>
---	-----------

*Robert Bigelow*

CHAPTER SIX

<b>Phase I Trials: First in Human .....</b>	<b>83</b>
---	-----------

*Kevin M. Watt, Karen Chiswell, and Michael Cohen-Wolkowiez*

CHAPTER SEVEN

<b>Phase II Clinical Trials .....</b>	<b>101</b>
---------------------------------------	------------

*Jeffrey T. Guptill and Karen Chiswell*

CHAPTER EIGHT

<b>Phase III and IV Clinical Trials.....</b>	<b>113</b>
--	------------

*Gail E. Hafley, Sergio Leonardi, and Karen S. Pieper*

CHAPTER NINE

<b>Challenges of Clinical Trials in Pediatrics .....</b>	<b>127</b>
--	------------

*Kevin N. Turner and P. Brian Smith*

**SECTION III: OBSERVATIONAL RESEARCH**

*Lesley H. Curtis and Laine E. Thomas, editors*

CHAPTER TEN

<b>Observational Research.....</b>	<b>143</b>
------------------------------------	------------

*Michaela A. Dinan*

CHAPTER ELEVEN

<b>Data Resources .....</b>	<b>157</b>
-----------------------------	------------

*Ying Xian*

CHAPTER TWELVE

<b>Observational Study Designs.....</b>	<b>169</b>
---	------------

*Bradley G. Hammill*

CHAPTER THIRTEEN	
<b>Challenges of Observational Designs .....</b>	<b>179</b>
<i>David M. Vock</i>	
CHAPTER FOURTEEN	
<b>Specific Regression Techniques.....</b>	<b>189</b>
<i>Phillip J. Schulte and Laine E. Thomas</i>	
CHAPTER FIFTEEN	
<b>Analytical Methods of Addressing Confounding .....</b>	<b>209</b>
<i>Eric M. Reyes and Laine E. Thomas</i>	
CHAPTER SIXTEEN	
<b>Lessons from Notable Examples in Observational Research.....</b>	<b>227</b>
<i>Zubin J. Eapen</i>	
<i>Index .....</i>	<b>237</b>