TRANSLATIONAL AND EXPERIMENTAL CLINICAL RESEARCH

DANIEL P. SCHUSTER WILLIAM J. POWERS



Contents

	Introduction	X
SEC	CTION I	
Pla	anning and Designing Clinical Research	1
1	Defining the Research Question	3
2	Searching the Literature	15
3	Variables and Measurements	31
4	Study Eligibility and Participant Selection	45
5	Recruiting Research Participants	54
6	Reducing Bias	67
7	Observational Study Designs	73
8	Experimental Study Designs	84
9	Estimating Sample Size	97
10	Database Development	113
11	Case Report Form Development	122
12	Data Collection and Quality Control	136
13	Monitoring Experimental Interventions	152
SEC	TION II	
	ecial Topics	161
14	Responsible Conduct of Research	 163
15	Regulatory Oversight	176
16	Funding Clinical Research	189
17	Research Budgeting	198
18	"Small" Clinical Experiments	203
19	Clinical Studies in Pediatric Minority Populations	209
20	Pharmacokinetics and Pharmacodynamics	212
21	Gene Therapy and Pharmacogenomic Studies	223
22	Preparing for Gene Therapy Studies	237

SECTION III

Analyzing and Reporting Results		247
23	Overview: Hypothesis Testing and Summary Statistics	249
24	Group Comparisons	258
25	Regression	271
26	Multivariate Analysis	284
27	Biostatistical Consulting	297
28	Statistical Computing	303
29	Presenting Data in Manuscripts	308
30	Visual Presentation of Data	320
	odern Techniques of Translational Clinical Research	331
31	Fundamentals of Gene Expression	333
32	Identifying Mutations and Polymorphisms	343
33	Cloning Methods	356
34	Transcriptional Profiling	369
35	Proteomics	385
36	Cell and Tissue Imaging Techniques	396
37	Non-Imaging Cell and Tissue Techniques and Tissue Banking	413
38		
	Evaluating Substrate Metabolism	435
39	Evaluating Substrate Metabolism Medical Images as Scientific Data	