

Contents

Preface.....	xiii
Acknowledgments.....	xv
Abbreviations	xvii
SECTION I. History and Background.....	1
Chapter 1. History and Background of Clinical Trials	3
SECTION II. Protocol Development	11
Chapter 2. Assurances	13
Chapter 3. Elements of a Protocol.....	17
Chapter 4. Workload Determination and Resource Allocation.....	21
Chapter 5. Budget.....	31
Chapter 6. Statistical Considerations in Protocol Development.....	41
SECTION III. Preparation and Assessment	49
Chapter 7. Safety Issues	51
Chapter 8. Sponsoring Agencies: Industry	55
Chapter 9. Potential Accrual Base	59
Chapter 10. Educating Staff	63
Chapter 11. Clinical Research/Interdisciplinary Team	69
SECTION IV. Legislative and Regulatory Issues	77
Chapter 12. Introduction to Legal and Regulatory Issues	79
Chapter 13. Institutional Review Boards/Protocol Modifications.....	91
Chapter 14. Informed Consent.....	97
Chapter 15. Compassionate Use of Investigational Drugs	107
Chapter 16. Conflicts of Interest.....	111
Chapter 17. Legislative Issues	115
Chapter 18. General Publication and Authorship Policies for Nurses.....	123
SECTION V. Promotion and Patient Retention.....	131
Chapter 19. Psychosocial Considerations.....	133
Chapter 20. Public and Patient Education	141
Chapter 21. Recruitment and Promotion Strategies for Clinical Trials.....	147
Chapter 22. Eligibility	151
Chapter 23. Designing a Computerized Tool to Verify Eligibility	155
Chapter 24. Prevention and Control Study Considerations.....	167
SECTION VI. Active Treatment	177
Chapter 25. Investigational Agents and Procurement of Research Study Drugs.....	179
Chapter 26. Administration of Protocol Agents	189
Chapter 27. Symptom Management in Clinical Trials Nursing	193
Chapter 28. Adverse Events.....	197
Chapter 29. Patient and Family Education	215
Chapter 30. Adherence in Clinical Trials	223
SECTION VII. Ancillary Studies	229
Chapter 31. Quality-of-Life Studies.....	231
Chapter 32. Pharmacokinetics, Pharmacodynamics, and Pharmacogenomics	235
Chapter 33. Genetic Testing and Storage of Genetic Material	243

Chapter 34. Pharmacoeconomic Studies	249
Chapter 35. Nursing Companion Studies	253
SECTION VIII. Off-Treatment Follow-Up	257
Chapter 36. Off-Treatment Protocol Considerations	259
Chapter 37. Long-Term Follow-Up	263
Chapter 38. Off-Treatment Documentation	267
SECTION IX. Data Management and Reporting	271
Chapter 39. The Need for Data Management Tools	273
Chapter 40. Documentation and Forms Submissions	287
Chapter 41. Electronic Data Capture in Clinical Trials	289
Chapter 42. Clinical Data Management Systems	293
Chapter 43. Cancer Trials Support Unit: A Service of the National Cancer Institute	301
Chapter 44. Clinical Trial Registries	305
SECTION X. Quality Management	313
Chapter 45. Good Clinical Practice	315
Chapter 46. Standard Operating Procedures	323
Chapter 47. Audit Preparation	329
Chapter 48. Community-Based Clinical Trials	335
Chapter 49. Drug Accountability	339
Chapter 50. Interdisciplinary Team Review	345
SECTION XI. Professional Development	351
Chapter 51. Specialization in Clinical Trials Nursing	353
Chapter 52. Mentorship	357
Chapter 53. Professional Continuing Education	363
SECTION XII. International Considerations	367
Chapter 54. Australia	369
Chapter 55. New Zealand	377
Chapter 56. Canada	383
Chapter 57. Japan	391
Chapter 58. European Union Directives	403
Chapter 59. Austria	409
Chapter 60. Denmark	413
Chapter 61. France	417
Chapter 62. Germany	421
Chapter 63. Italy	429
Chapter 64. United Kingdom	439
Appendices	451
Appendix 1. Nuremberg Code	453
Appendix 2. Declaration of Helsinki	454
Appendix 3. National Research Act, Public Law 93-348, July 12, 1974	456
Appendix 4. The Belmont Report	457
Appendix 5. Code of Federal Regulations	463
Appendix 6. International Conference on Harmonisation Guideline for Good Clinical Practice	476
Appendix 7. Federalwide Assurance Terms	501
Appendix 8. Federalwide Assurance Template	507
Appendix 9. Individual Investigator Agreement	509
Appendix 10. Informed Consent Document Template	510
Appendix 11. National Cancer Institute Return Agent Form	520
Appendix 12. National Cancer Institute Transfer Investigational Agent Form	521
Appendix 13. Internet Resource List	522
Index	525