

Good Clinical Practice Guide Table of Contents

Chapter 1: EXECUTIVE SUMMARY	7
Chapter 2: INTRODUCTION.....	11
The Phases of Clinical Study.....	11
Clinical Trial Design and Analysis.....	13
Corporate Implications of Non-compliance with GCP.....	17
Chapter 3: INTERNATIONAL REGULATIONS GOVERNING GCP	18
History of GCP Legislation.....	18
Current Regulations	20
Chapter 4: THE ELEMENTS OF GCP COMPLIANCE.....	32
Standard Operating Procedures as Tools for GCP Compliance.....	34
Chapter 5: THE SPONSOR—DUTIES AND RESPONSIBILITIES	39
General Responsibilities of the Sponsor	39
Trial Design and Management.....	42
Investigator Selection and Assignment of Duties and Functions.....	45
Compensation and Financing	46
Submissions to Regulatory Authorities.....	48
Investigator’s Brochure.....	49
Investigational Drug Products	49
Record Access.....	51
Safety Information and Adverse Drug Effects Reporting.....	51
Annual Reports	51
Study Monitoring.....	52
Regional Variations of Sponsor’s GCP Responsibilities	54
Chapter 6: THE CLINICAL INVESTIGATOR—DUTIES AND RESPONSIBILITIES	56
Qualifications and Agreements.....	56
Investigational Drug Products	59
Clinical Study Design	60

Informed Consent.....	60
Records and Reports	65
Premature Trial Termination or Suspension.....	71
Regional Variations of Investigator’s GCP Responsibilities	72
Chapter 7: THE INSTITUTIONAL REVIEW	
BOARD/INDEPENDENT ETHICS COMMITTEE.....	73
Responsibilities.....	74
Composition and Operations	74
Review Procedures.....	76
Subject Recruitment Advertising.....	77
Informed Consent Form	79
Department of Health and Human Services Regulations.....	80
Records.....	81
Regional Variations of IRB Duties and Responsibilities.....	81
Chapter 8: THE INVESTIGATOR’S BROCHURE.....	83
General Considerations	83
Brochure Contents.....	83
Chapter 9: THE CLINICAL TRIAL PROTOCOL.....	86
General Information.....	86
Background Information	87
Study Purpose and Objectives	88
Study Design.....	88
Selection, Withdrawal, and Treatment of Subjects.....	89
Assessments of Efficacy and Safety	90
Statistical Analyses	91
Other Provisions.....	91
Data Handling and Record Keeping—Computerized Systems.....	92
Protocol Amendments.....	97
Chapter 10: ESSENTIAL DOCUMENTS FOR TRIAL CONDUCT.....	98
Before the Trial.....	98

During the Clinical Phase.....	100
After Completion or Termination.....	102
Chapter 11: INTERNAL AND EXTERNAL MONITORING AND	
INSPECTIONS.....	104
Sponsor’s Monitoring.....	104
Selection and Qualification of Monitors.....	104
Extent and Nature of Monitoring.....	105
Monitor’s Responsibilities.....	106
Sponsor’s Study Audit.....	110
Clinical Data Monitoring Committees.....	112
Regulatory Inspections.....	114
How to Cope with Audits and Inspections.....	122
Appendix 1. CHECKLISTS AND FORMS FOR MONITORING AND	
AUDITS.....	130
Appendix 2. FURTHER READING.....	153
Advisory Bodies, Publications and Web Sites.....	153
References.....	155