

SOPS FOR GCP-COMPLIANT CLINICAL TRIALS

A CUSTOMIZABLE MANUAL FOR SITES



SOPS FOR GCP-COMPLIANT CLINICAL TRIALS

A CUSTOMIZABLE MANUAL FOR SITES

SOP Manual for Compliance with ICH Good Clinical Practice Guidelines
and FDA Regulations at the Investigative Site



© CenterWatch 2019

© 2019 CenterWatch. Digital version ISBN: 978-1-60430-097-0. Price: \$695.00. All rights reserved. Photocopying or reproducing this report in any form, including electronic or facsimile transmission, scanning or electronic storage, is a violation of federal copyright law and is strictly prohibited without the publisher's express written permission. This report may not be resold. CenterWatch only sells its publications directly or through authorized resellers. Information concerning authorized resellers may be obtained from CenterWatch, 300 N. Washington St., Suite 200, Falls Church, VA 22046-3431. Main telephone: 617.948.5100. Toll free: 866.219.3440.

While every effort has been made by CenterWatch to ensure the accuracy of information in this publication, this organization accepts no responsibility for errors or omissions. The publication is sold as is, without warranty of any kind, either express or implied, respecting its contents, including but not limited to implied warranties for the publication's quality, performance, merchantability, or fitness for any particular purpose. Neither CenterWatch nor its dealers or distributors shall be liable to the purchaser or any other person or entity with respect to any liability, loss, or damage caused or alleged to be caused directly or indirectly by this publication.

TABLE OF CONTENTS

INTRODUCTION.....	1
Editing the Template.....	3
About the Author	3
LIST OF ABBREVIATIONS.....	5
GLOSSARY	7
I. GA-100 GENERAL ADMINISTRATION.....	23
SOP GA 101 Assuming and Fulfilling Responsibility for GCP.....	25
SOP GA 102 Document Development and Change Control.....	33
SOP GA 103 Ensuring Qualified Site Personnel and Research Staff.....	37
SOP GA 104 Contracts.....	43
SOP GA 105 Records Management, Accountability and Retention.....	47
II. RA-200 REGULATORY AFFAIRS.....	55
SOP RA 201 Essential Documents	57
SOP RA 202 Initial and Ongoing Submissions	61
SOP RA 203 Reporting Requirements	67
SOP RA 204 Conflict of Interest	71
III. PM-300 PROJECT MANAGEMENT	75
SOP PM 301 Assessing Study Feasibility	77
SOP PM 302 Study Start-Up.....	85
SOP PM 303 Investigational Product Management.....	93
SOP PM 304 Source Documentation	97
SOP PM 305 Monitoring Visits	101
SOP PM 306 Study Completion.....	107
SOP PM 307 Compliance with Protocol	111
IV. SM-400 SUBJECT MANAGEMENT	115
SOP SM 401 Subject Recruitment, Screening and Retention	117
SOP SM 402 Informed Consent/Assent	125
SOP SM 403 Eligibility and Enrollment	137
SOP SM 404 Protecting Confidential Information	143
SOP SM 405 Subject Visits and Assessments.....	149
SOP SM 406 AE Management.....	157
V. DM-500 DATA MANAGEMENT.....	163
SOP DM 501 Clinical Data Management.....	165

SOP DM 502 Use of Electronic Data Management Systems..... 169

VI. QA-600 QUALITY ASSURANCE 175

SOP QA 601 Quality Assurance Audits..... 177

SOP QA 602 Inspections by Regulatory Authorities..... 183

VII. AT-701 ATTACHMENTS..... 187

LIST OF ATTACHMENTS..... 189

VIII. APPENDIX A REGULATORY RESOURCES..... 399

© CenterWatch 2019