

REPORTING PROTOCOL DEVIATIONS

As a Research Ethics Board, the RvH REB's primary responsibility is to protect the safety and rights of human research participants, and therefore the REB must be aware of situations that place research participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized or as identified in the approved protocol.

The term protocol deviation is not well defined by regulations or guidelines but deviations are identified as any unplanned or unforeseen change to a REB approved protocol or protocol procedures. Deviations are different from amendments in that they generally apply to a single occurrence or participant and are not intended at the time to modify the entire protocol. Amendments are changes to the protocol or protocol procedures that are planned and that are approved by the REB prior to implementation.

There have been attempts to categorize protocol deviations as major versus minor and/or to distinguish between deviations and violations; however, there is no clear guidance on these distinctions. There are, however, guidelines and requirements for reporting protocol deviations. Examples of protocol deviations that should be reported to the REB include the following:

- Implementation of additional procedures for monitoring participants;
- Suspension of enrollment of new participants;
- Suspension of research procedures in currently enrolled participants.

If an unanticipated deviation or divergence from the approved research protocol, consent document(s) or study addenda jeopardizes participant safety, study efficacy or data integrity, it must be **promptly** reported to the REB using the attached reporting form. Specific examples of reportable deviations (i.e., if they place participants at a greater risk):

- Informed consent improperly obtained or not obtained;
- Emergency deviations to the research protocol initiated by the investigator prior to obtaining REB approval to (e.g., to eliminate apparent immediate hazards to participants);
- Major, non-emergent deviations without prior approval;
- Participant enrolment without meeting the eligibility criteria and without prior sponsor approval;
- Study drug or dose not administered per protocol with increased risk of harm to participant.

If a protocol deviation meets the reportable criteria and has not otherwise been reported through an amendment to the protocol or consent form, it should be reported to the REB using the Protocol Deviation Reporting Form. Protocol Deviations that lead to an SAE should be reported within 48 hours, otherwise within 10 working days.

***Note:** Research agreements may require the PI to notify the sponsor of all unplanned deviations or departures from REB approved protocol procedures. Sponsor reporting requirements for deviations may differ from the REB's reporting requirements. It is the PI's responsibility to comply with the reporting requirements outlined in the signed contract.*

Resources:

1. Office for Human Research Protections (OHRP) Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Participants or Others and Adverse Events www.hhs.gov/ohrp/policy/AdvEventGuid.htm
2. ICH Good Clinical Practice Guidelines, Section 3.3.7 & Section 4.5.1 – 4.5.5
3. Goldfarb, Norman M. Directory of Protocol Deviation & Violation (PDV) Codes: A Lexicon for Understanding & Communicating Protocol Deviations & Violations. First Clinical Research. www.firstclinical.com/resources/codes
4. Protocol Violations: Implications for Clinical Research" Clinical Research Focus, 12(7) Oct 2001

Format For Protocol Deviation Report

Salah M. Abdel-aleem



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Design, Execution, and Management of Medical Device Clinical Trials Salah M. Abdel-aleem, 2009-08-19 An essential introduction to conducting the various stages of medical device clinical trials Clinical research continues to be one of the most vital components of pharmaceutical biostatistical and medical studies Design Execution and Management of Medical Device Clinical Trials provides a uniform methodology for conducting and managing clinical trials Written in a style that is accessible to readers from diverse educational and professional backgrounds this book provides an in depth and broad overview for successfully performing clinical tasks and activities Throughout the book practical examples compiled from both the author s and other researchers previous clinical trial experiences are discussed in a sequential manner as they occur in the study starting from the development of the clinical protocol and the selection of clinical sites and ending with the completion of the final clinical study report Next readers are guided through the development of important clinical documents including informed consent forms case report forms and study logs A careful review of the Food and Drug Administration FDA and International Conference on Harmonisation ICH regulations applicable to medical devices is also featured Additional coverage includes Qualification and selection of investigators Study monitoring visits Definitions and reporting procedures for adverse events The use of biostatistical methodology in clinical research including the use of biostatistics for sample size determination and study endpoints The roles and responsibilities of all members of a clinical research team The book concludes with an insightful discussion of special ethical conduct for human research and challenging issues to consider during the design of clinical studies A glossary lists important clinical and statistical terms used in clinical research and an extensive reference section provides additional resources for the most up to date literature on the topic Design Execution and Management of Medical Device Clinical Trials is an excellent book for clinical research or epidemiology courses at the upper undergraduate and graduate levels It is also an indispensable reference for clinical research associates clinical managers clinical scientists biostatisticians pharmacologists and any professional working in the field of clinical research who would like to better understand clinical research practices The Design and Management of Medical Device Clinical Trials Salah M. Abdel-aleem, 2011-09-09 Clinical trials tasks and activities are widely diverse and require certain skill sets to both plan and execute This book provides professionals in the field of clinical research with valuable information on the challenging issues of the design execution and management of clinical trials and how to resolve these issues effectively It discusses key obstacles such as challenges to patient recruitment investigator and study site selection and dealing with compliance issues Through practical examples professionals working with medical device clinical trials will discover the appropriate steps to take *Good Clinical, Laboratory and Manufacturing Practices* Phillip A. Carson, Nigel J. Dent, 2007 Provides practical advice for the quality assurance professional responsible for monitoring compliance with legal requirements and accepted standards of preclinical safety studies clinical trials and manufacture of

drugs This book also offers a framework for integrating these standards with other quality management systems

Handbook for Clinical Research Flora Hammond, James Malec, Todd G. Nick, 2014-08-26 With over 80 information packed chapters Handbook for Clinical Research delivers the practical insights and expert tips necessary for successful research design analysis and implementation Using clear language and an accessible bullet point format the authors present the knowledge and expertise developed over time and traditionally shared from mentor to mentee and colleague to colleague Organized for quick access to key topics and replete with practical examples the book describes a variety of research designs and statistical methods and explains how to choose the best design for a particular project Research implementation including regulatory issues and grant writing is also covered The book opens with a section on the basics of research design discussing the many ways in which studies can be organized executed and evaluated The second section is devoted to statistics and explains how to choose the correct statistical approach and reviews the varieties of data types descriptive and inferential statistics methods for demonstrating associations hypothesis testing and prediction specialized methods and considerations in epidemiological studies and measure construction The third section covers implementation including how to develop a grant application step by step the project budget and the nuts and bolts of the timely and successful completion of a research project and documentation of findings procedural manuals and case report forms collecting managing and securing data operational structure and ongoing monitoring and evaluation and ethical and regulatory concerns in research with human subjects With a concise presentation of the essentials for successful research the Handbook for Clinical Research is a valuable addition to the library of any student research professional or clinician interested in expanding the knowledge base of his or her field Key Features Delivers the essential elements practical insights and trade secrets for ensuring successful research design analysis and implementation Presents the nuts and bolts of statistical analysis Organized for quick access to a wealth of information Replete with practical examples of successful research designs from single case designs to meta analysis and how to achieve them Addresses research implementation including regulatory issues and grant writing

Early Drug Development Mitchell N. Cayen, 2011-02-25 The focus of early drug development has been the submission of an Investigational New Drug application to regulatory agencies Early Drug Development Strategies and Routes to First in Human Trials guides drug development organizations in preparing and submitting an Investigational New Drug IND application By explaining the nuts and bolts of preclinical development activities and their interplay in effectively identifying successful clinical candidates the book helps pharmaceutical scientists determine what types of discovery and preclinical research studies are needed in order to support a submission to regulatory agencies Handbook of Modern Pharmaceutical Analysis Satinder Ahuja, Stephen Scypinski, 2001-08-02 This book describes the role modern pharmaceutical analysis plays in the development of new drugs Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug Coverage includes state of the art topics such as analytics

for combinatorial chemistry and high throughput screening formulation development stability studies international regulatory aspects and documentation and future technologies that are likely to impact the field Emphasis is placed on current easy to follow methods that readers can apply in their laboratories No book has effectively replaced the very popular text *Pharmaceutical Analysis* that was edited in the 1960s by Tak Higuchi This book will fill that gap with an up to date treatment that is both handy and authoritative

Quick Guide to Good Clinical Practice Cemal Cingi,Nuray Bayar Muluk,2016-11-15 This brand new book offers a reference guide to understanding and applying the rules for properly conducting clinical trials to meet the international quality standard Good Clinical Practice provided by the International Conference on Harmonization ICH The work offers an updated perspective on the clinical research landscape within the context of the clinical trial regulatory frameworks in Europe and the USA In addition to providing a historical review and a detailed definition of GPC regulations it includes step by step explanations of all the requirements that researchers should bear in mind when designing and performing new trials Further topics covered include ethics of clinical research the drug development process and evolution of regulations investigator and sponsor responsibilities and clinical trial protocols Written by clinicians for clinicians the book represents a valuable read also for researchers pharmacists and all professionals involved in applications to the ethic committees whose approval is required for new clinical studies

Modern Pharmaceutical Analytical Techniques Mr. Rohit Manglik,2024-07-04 EduGorilla Publication is a trusted name in the education sector committed to empowering learners with high quality study materials and resources Specializing in competitive exams and academic support EduGorilla provides comprehensive and well structured content tailored to meet the needs of students across various streams and levels

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