

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

Kathleen Armour



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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, MD, James F. Malec, Todd Nick, Ralph Buschbacher, MD, 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

[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 *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

Vaccines for Biodefense and Emerging and Neglected Diseases Alan D.T. Barrett,Lawrence R. Stanberry,2009-03-05 The last 20 years has seen a rapid increase in infectious diseases particularly those that are termed emerging diseases such as SARS neglected diseases such as malaria and those that are deemed biothreats such as anthrax It is well recognized that the most effective modality for preventing infectious diseases is vaccination This book provides researchers with a better understanding of what is currently known about these diseases including whether there is a vaccine available or under development It also informs readers of the key issues in development of a vaccine for each disease Provides a comprehensive treatise of the agents that are responsible for emerging and neglected diseases and those that can be used as biothreats Includes the processes such as the vaccine development pathway vaccine manufacturing and regulatory issues that are critical to the generation of these vaccines to the marketplace Each chapter will include a map of the world showing where that particular disease is naturally found **Good Clinical, Laboratory and Manufacturing Practices** Philip Carson,Nigel Dent,2007-10-31 Quality assurance and good laboratory practices are becoming essential knowledge for professionals in all sorts of industries This includes internal and external audit procedures for compliance with the requirements of good clinical laboratory and manufacturing practices Spanning chemical cosmetic and manufacturing industries *Good Clinical Laboratory and Manufacturing Practices Techniques* for the QA professional is aimed at chemists clinicians ecotoxicologists operation managers pharmaceutical process managers quality assurance officers technicians and toxicologists In addition sections on harmonisation of quality systems will be of value to safety health and environment advisors This comprehensive and high level reference will be an indispensable guide to research laboratories in academia and industry Additional training material is also included *Research Regulatory Compliance* Mark A. Suckow,Bill

Yates,2015-06-14 Research Regulatory Compliance offers the latest information on regulations and compliance in the laboratory With the increasing complexity of regulations and need for institutional infrastructure to deal with compliance of animal use issues as well as a requirement surrounding human subjects this publication provides reputable guidance and information The book is extremely helpful as a resource for researchers administrators and technicians in the laboratory and is also a great asset for faculty or new researchers coming in to the laboratory environment It will help prepare users for the deluge of regulatory and compliance issues they will face while conducting their scientific programs The book is edited and authored by known leaders in the field of compliance and regulations and contains extensive research on the topics It represents the new standard for information in every laboratory Provides a one stop go to resource for the many regulatory and compliance issues that affect laboratory study and research models Extremely helpful as a resource for researchers administrators and technicians in the laboratory and also a great asset for faculty or new researchers coming in to the laboratory environment Focuses on United States regulations covering both animal models and human subjects Written and edited by known leaders in the field of regulatory compliance who bring many years of collective experience to the book

Cancer Treatment Reports ,1987 **Research Ethics in Africa** Mariana Kruger,Paul Ndebele,Lyn Horn,2014-06-01 The aim of this book is to provide research ethics committee members with a resource that focuses on research ethics issues in Africa The authors are currently active in various aspects of research ethics in Africa and the majority have been trained in the past by either the Fogarty International Center or Europe and Developing Countries Clinical Trial Partnership EDCTP sponsored bioethics training programmes **Cost-Contained Regulatory Compliance** Sandy Weinberg,2011-04-18 This book guides the reader through FDA regulation guidelines and outlines a comprehensive strategy for cost reduction in regulatory affairs and compliance This book explains six strategies to cost effectively comply with FDA regulations while maintaining product safety and improving public access through cost controls It provides useful and practical guidance through industry case studies from pharmaceutical biotech and medical device industries Institutional Review Board: Management and Function Public Responsibility in Medicine & Research (PRIM&R),,Elizabeth A. Bankert,Bruce G. Gordon,Elisa A. Hurley,2021-03-01 Institutional Review Board IRB members and oversight personnel face challenges with research involving new technology management of big data globalization of research and more complex federal regulations Institutional Review Board Management and Function Third Edition provides everything IRBs and administrators need to know about efficiently managing and effectively operating a modern and compliant system of protecting human research subjects This trusted reference manual has been extensively updated to reflect the 2018 revisions to the Federal Policy for the Protection of Human Subjects Common Rule An essential resource for both seasoned and novice IRB administrators and members Institutional Review Board Management and Function provides comprehensive and understandable interpretations of the regulations clear descriptions of the ethical principles on which the regulations are based and practical step by step

guidance for effectively implementing regulatory oversight *Generic Drug Product Development* Leon Shargel,Isadore Kanfer,2013-10-24 In this era of increased pharmaceutical industry competition success for generic drug companies is dependent on their ability to manufacture therapeutic equivalent drug products in an economical and timely manner while also being cognizant of patent infringement and other legal and regulatory concerns *Generic Drug Product Development Solid Oral The Fundamentals of Clinical Research* P. Michael Dubinsky,Karen A. Henry,2022-01-26 This book focuses on the practical application of good clinical practice GCP fundamentals and provides insight into roles and responsibilities included in planning executing and analyzing clinical trials The authors describe the design of quality into clinical trial planning and the application of regulatory scientific administrative business and ethical considerations Describes the design of quality into the clinical trial planning Has end of chapter questions and answers to check learning and comprehension Includes charts that visually summarize the content and allow readers to cross reference details in relevant chapters Offers a companion website containing supplemental training resources *Handbook of Validation in Pharmaceutical Processes, Fourth Edition* James Agalloco,Phil DeSantis,Anthony Grilli,Anthony Pavell,2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations *Handbook of Validation in Pharmaceutical Processes Fourth Edition* examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry s leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes *Handbook of Validation in Pharmaceutical Processes Fourth Edition* is essential for all global health care manufacturers and pharmaceutical industry professionals **Key Features** Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores distinctive and specific process steps and identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture **Dictionary of Pharmaceutical Medicine** Gerhard Nahler,2017-03-17 This dictionary defines various terms typically used in pharmaceutical medicine A new 4th edition includes adaptations of the text to the steadily increasing regulatory requirements particularly in the area of genetics gene therapy product quality e g protection against falsified medicines and of product safety pharmacovigilance Further evolving areas that are covered by the 4th edition are typical grey zones health effects often borderline to medicinal products such as cosmetics and dietary supplements where misleading information is prohibited on one hand but where any health claims need formal authorisation on the other These but also other areas are reviewed and presented in an updated and if justified in an enlarged form Handbook: The Duty for Sponsor Oversight in

Clinical Trials Doris Breiner, 2025-01-20 The next edition of the practical guide with regard to The Duty for Sponsor Oversight in Clinical Research was prepared to present in more detail the Risk Based Operational Data Review As outlined in the previous edition of the practical guide the definition of a threshold for missing data and or values was not explicit outlined in the applicable regulatory binding documents for example the Clinical trials Regulation EU No 536/2014 This is also applicable for the upper limit or level of acceptance of for example protocol deviations missing values and or values out of range or missing safety visits Nevertheless the underlying regulations as well as reflexion papers and other articles provide the overall guidance and required information for the determination of relevant protocol deviations serious breaches and other deviations or issues These should normally aligned to the defined outcome parameters of a clinical trial The same applies for the patient safety data integrity and data protection Therefore the supplement edition was prepared for proposing a separate risk based operational review The aim includes enhancing with the assumed procedure the quality of the data set as required for example the AMNOG procedure in Germany and or accelerated approval

Handbook: The Duty for "Sponsor Oversight" in Clinical Research Doris Breiner, 2022-07-11 The evidence that the sponsor of a clinical trial fulfills the obligation to perform oversight of e.g. a CRO that carries out outsourced study activities on behalf of the sponsor is not new Nevertheless the addendum to the ICH GCP has explicitly included this as a sponsor responsibility under point 5.2.2 It applies to all sponsors of a clinical trial independent of the kind of the clinical trial whether commercial or academic study if the study activities are outsourced to a CRO The goal is to ensure the patient safety and data integrity The review of the sponsor's oversight is also subject to e.g. an inspection by an authority The first edition of this manual is based on a master's thesis within the framework of the university master's program Clinical Research The concept developed is certainly not completely new but is based inter alia to already discussed measures or publications as example by the English authority MHRA It is intended to serve as an example to illustrate how the sponsor's duty of supervision can be implemented simply and efficiently in rather small medium sized companies Of course every company has to decide for itself how to implement it

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