

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 enrolment 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

Karin Nielsen-Saines



Format For Protocol Deviation Report:

The book delves into Format For Protocol Deviation Report. Format For Protocol Deviation Report is a crucial topic that needs to be grasped by everyone, ranging from students and scholars to the general public. The book will furnish comprehensive and in-depth insights into Format For Protocol Deviation Report, encompassing both the fundamentals and more intricate discussions.

1. This book is structured into several chapters, namely:
 - Chapter 1: Introduction to Format For Protocol Deviation Report
 - Chapter 2: Essential Elements of Format For Protocol Deviation Report
 - Chapter 3: Format For Protocol Deviation Report in Everyday Life
 - Chapter 4: Format For Protocol Deviation Report in Specific Contexts
 - Chapter 5: Conclusion
2. In chapter 1, this book will provide an overview of Format For Protocol Deviation Report. This chapter will explore what Format For Protocol Deviation Report is, why Format For Protocol Deviation Report is vital, and how to effectively learn about Format For Protocol Deviation Report.
3. In chapter 2, this book will delve into the foundational concepts of Format For Protocol Deviation Report. This chapter will elucidate the essential principles that must be understood to grasp Format For Protocol Deviation Report in its entirety.
4. In chapter 3, the author will examine the practical applications of Format For Protocol Deviation Report in daily life. The third chapter will showcase real-world examples of how Format For Protocol Deviation Report can be effectively utilized in everyday scenarios.
5. In chapter 4, the author will scrutinize the relevance of Format For Protocol Deviation Report in specific contexts. This chapter will explore how Format For Protocol Deviation Report is applied in specialized fields, such as education, business, and technology.
6. In chapter 5, the author will draw a conclusion about Format For Protocol Deviation Report. This chapter will summarize the key points that have been discussed throughout the book.

This book is crafted in an easy-to-understand language and is complemented by engaging illustrations. It is highly recommended for anyone seeking to gain a comprehensive understanding of Format For Protocol Deviation Report.

<https://staging.conocer.cide.edu/About/uploaded-files/default.aspx/Heart%20Of%20Names.pdf>

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