N2 NETWORK OF NETWORKS
RÉSEAU DES RÉSEAUX
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PROTOCOL DEVIATIONS!

N2 HEALTH CANADA INSPECTION SURVEY RESULTS FOR PROTOCOL DEVIATIONS

"An ounce of prevention is worth a pound of cure." *– Benjamin Franklin*

Based on the 14 organizations that responded to the N2 Health Canada Inspection Survey, Health Canada inspectors cited 12 observations related to protocol deviations.

REGULATION	NUMBER OF OBSERVATIONS	
	Risk 2 (Major)	Risk 3 (Minor)
C.05.010 (b) – Trial is conducted according to protocol	8	1
C.05.010 (j) – Drug is being manufactured, handled, and stored in accordance with GMP.	1	0
C.05.012 (1) – Maintaining complete, accurate, and verifiable records	0	1
C.05.012 (2) – Maintaining records according to GCP	1	0

Protocol Deviations occur when research veers from the approved protocol during the course of a trial. This could be planned (avoiding potential harm) or unplanned (error or oversight). Certain deviations can have a significant impact ranging from participant safety to affecting data integrity. It is important to take a moment at the beginning of a trial to develop a plan on how you will handle protocol deviations when they occur. For example, what action could you take if you notice a subset of participants continually miss the 6-month follow up visit?

The investigator should not intentionally deviate from the approved protocol without prior approval from the Sponsor and REB. The exception to this is if the deviation is to remove an immediate hazard to the participant (ICH/GCP 4.5).

DID YOU KNOW?

1) ICH/GCP and Health Canada do not define the term protocol deviation. Therefore, organizations often develop their own definition and establish the reporting requirements.
2) Excessive protocol deviations may result in participant harm and introduce errors into a clinical trial's results leading to flawed trial conclusions.

This information sheet has been created by the N2 Quality Committee. For more information Contact Us at hsenechal@ohri.ca.

TIPS AND HINTS

1) A well-written protocol is key! Take the time to ensure stakeholders review and provide feedback. Think of the logistics of rolling out the protocol in your area – will it work? Will it work for your multi-center sites? Are the eligibility criteria feasible? Work flexibility into your protocol where possible.
2) Risk Identification: Take time at the start of a study to identify potential deviations. Review the list regularly, it may change over time!
3) Risk Analysis: for the deviations identified, rate them from low impact to your study to critical impact and include an assessment on the probability of occurrence.
4) Risk Mitigation: Develop a plan to control for these potential deviations. Focus on those critical to your study. **Plan for the unexpected!** The process should be flexible to handle deviations that you did not anticipate.
5) Track the number and type of deviations that have occurred for the whole trial, not just in individual participant source documents. This will help you identify **TRENDS** that may trigger the need for a protocol amendment.
6) Report the protocol deviations as per your sponsors and/or institutions procedures.

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