N2 NETWORK OF NETWORKS
RÉSEAU DES RÉSEAUX
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DELEGATION LOGS

N2 HEALTH CANADA INSPECTION SURVEY RESULTS FOR DELEGATION LOGS:

According to the Health Canada pre-inspection package, the Health Canada inspectors review the delegation of responsibilities log so they can identify the key study personnel and their delegated responsibilities, and review their education, training and experience.

Based on the 14 organizations that responded to the N2 Health Canada Inspection Survey, Health Canada inspectors cited 20 observations related to delegation logs.

REGULATION	NUMBER OF OBSERVATIONS	
	Risk 2 (Major)	Risk 3 (Minor)
C.05.010 (c) – Systems and Procedures	1	11
C.05.010 (g) – Training and Qualifications	2	3
C.05.010 (i) – Maintaining records according to C.05.012	0	1
C.05.012 (1) – Maintaining complete, accurate, and verifiable records	0	1
C.05.012 (2) – Maintaining records according to GCP	0	1

DID YOU KNOW?

1) There are some trial-related responsibilities that the Qualified Investigator (QI) cannot delegate:
   - Overall responsibility for the trial
   - Signing off on and agreeing to the conditions on the Qualified Investigator Undertaking Form
2) The following trial-related responsibilities can be delegated only to physicians:
   - Determining the causality and severity of an adverse event
   - Confirmation of eligibility criteria
   - Medical decisions, diagnoses, and physical exams*

   **unless these tasks are within a licensed professional's scope of practice*

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

TOP TEN TIPS FOR AVOIDING INSPECTION OBSERVATIONS RELATED TO DELEGATION LOGS!

1) Adapt the legend in the N2 delegation log template to suit your protocol. *For example, if the trial is not blinded, remove unblinding from the legend so it is not inadvertently assigned.*
2) Physical exam, confirmation of eligibility, AE **assessment**, and medical care/decisions must ONLY be delegated to qualified physicians.
3) Include clinical personnel performing significant trial related tasks on the delegation log. *For example, personnel administering the investigational product, performing randomization, or performing temperature monitoring.*
4) Everyone listed on the delegation log must provide evidence of training related to his or her role in the trial. This includes training on the protocol, study procedure manuals, SOPs, GCP, and the regulations, as applicable. Inspectors will verify the training and qualifications for each delegated task to ensure individuals are qualified.
5) The Qualified Investigator (QI) must provide trial oversight as evidenced by their signature and date for the start and end dates for each research team member. Any changes to the log must be initialed and dated by the QI.
6) Since the log is a delegation from the QI, there is no need to list the QI on the log itself. **However, this can be sponsor specific.**
7) Do not include scientists who had intellectual input into the development of the protocol if they are not performing any trial related tasks.
8) For investigator initiated multi-center trials, it is the sponsor's responsibility to collect each site's delegation log to verify accuracy and confirm training.
9) It's a good idea to have each research team member complete their own entries on the log; including trial tasks, printed name, signature, initials, and date. This proves the acceptance of the delegation and allows verification of handwriting on source documents.
10) **REVIEW REGULARLY FOR ACCURACY** – Ensure the log is kept current for the duration of the trial. Do not just file away after site initiation!

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