N2 NETWORK OF NETWORKS
RÉSEAU DES RÉSEAUX
Canada's alliance for excellence in clinical research

TRAINING

N2 HEALTH CANADA INSPECTION SURVEY RESULTS FOR TRAINING:

In accordance with ICH-GCP and Health Canada Food & Drug Regulations:

- ***The investigator should have an adequate number of qualified personnel and adequate resources for the duration of the study to conduct the study properly and safely;***
- ***Each individual involved in a clinical study must be qualified by education, training, and experience to perform his or her respective task(s);***

As indicated in the Health Canada pre-inspection package, the Health Canada inspectors will review and verify the following:

- ***The identification of key personnel and their delegated responsibilities;***
- ***The adequacy of their education, training and experience;***
- ***The Qualified Investigator's (QI) medical oversight of the participants and supervision of the research team;***

Based on the 14 organizations that responded to the N2 Health Canada Inspection Survey, Health Canada inspectors cited 15 observations related to training.

REGULATION	NUMBER OF OBSERVATIONS	
	Risk 2 (Major)	Risk 3(Minor)
C.05.010 (c) – Systems and Procedures	3	0
C.05.010 (g) – Training and Qualifications	11	1

DID YOU KNOW?

1) Study personnel are to be trained in:
   - ICH-Good Clinical Practice
   - Health Canada, Division 5 –pay particular attention to delegated tasks
   - Study protocol – to be completed before the study-related task is delegated
   - Study procedures – e.g. drug accountability
2) Administrative personnel are to be trained as appropriate to their delegated, study-related tasks (e.g. temperature monitoring)

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

TOP TEN TIPS FOR AVOIDING INSPECTION OBSERVATIONS RELATED TO TRAINING!

1) Create a training file for each individual on the delegation log – include all relevant training.
2) Document training for all delegated tasks.
3) Keep certificates of training – be mindful of expiry dates – retraining may be required!
4) For group training, maintain a log of attendance with the signatures of attendees; attach an agenda and/or slide deck.
5) Ensure tasks are delegated within the scope of the professional license, and that any additional training, as required by the delegated task, has been obtained.
6) If study personnel include foreign trained health professionals or other non-licensed professionals, delegated tasks must be within the scope of the provincial regulations and there must be documented evidence that the QI has observed the individual perform the task and has verified that the individual has demonstrated the appropriate knowledge, skill and judgment to perform the delegated task.
7) Create a Standard Operating Procedure on training for your site/organization – include requirements for ICH-GCP and SOP training.
8) If using the N2 SOPs, take advantage of the SOP quizzes as evidence of completed training.
9) The N2 GCP and Division 5 online courses though CITI Canada count towards evidence of training – take them today!
10) **REMEMBER** – while the QI is ultimately responsible, the research team must work together to ensure there is documented evidence of training!

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