Introduction

Staff training is a high priority in the CTN and the training process assumes the collaborative involvement of all parts of the CTN. High quality training for all personnel involved in the CTN is essential for successful protocol implementation, accurate data collection, and evaluation of study outcomes. This policy emphasizes the readiness of all CTN staff to implement studies in compliance with the Good Clinical Practice (GCP) guidelines of the International Conference on Harmonization (ICH) and NIH policies on the conduct of clinical trials.

Policies

- Individuals participating in the conduct of CTN studies will receive training as required according to their needs to be ready to work on the pertinent protocols.
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- Uniform requirements for Core training across all nodes include Good Research Practice/ Ethics and Common Assessment Battery.
- Node Principal Investigator (PI) will develop plans for Core training within his/her node according to CTN requirements.
- Protocol Lead Investigator will develop project training plan(s) according to protocol requirements.
- All protocol training plans must be reviewed by the Training Subcommittee and approved by the Steering Committee prior to submission of the protocol to the Protocol Review Board.
- Protocol LI and Node PI will collaborate in ensuring that participating staff received required training prior to protocol implementation according to training plan.
- Appointed individuals (trainers) will implement the training plans.
- All training will be evaluated according to standards specified in training plan.
- Individuals who receive training will receive documentation of participation.
- The CTN (through the Training Subcommittee and protocol committees) will develop and maintain training materials that will be available throughout the network..
- A representative from each node will be a member of the training subcommittee and serve as the conduit for communication and implementation of training activities between the node and training subcommittee.

Responsibilities of Training Subcommittee

- Develop curriculum and materials for Core training
- Develop a standardized protocol training plan template
- Review and provide recommendations for protocol training plans submitted
- Set standards for assessment of trainee competence in Core training
- Develop mechanism to document training activities and recognize participants
- Evaluate satisfaction of trainees according to standards of training plan
- Monitor and document training plan implementation across sites
- Serve as resource for training activities in the CTN
- Report regularly to the Steering Committee