

Training of Clinical Research Personnel

Procedure Overview

To define the standard procedures and documentation for training of clinical research personnel participating in research activities within the NETT network.

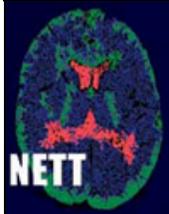
Responsible Individuals

Qualified NETT and Hub Complex personnel; Contracted Clinical Research Associates; NETT Director of Site Operations and/or designee.

Procedure

1. Documentation of training for NETT Personnel
 - a. Adequate training is required by the principles of the International Conference on Harmonization (ICH), Guideline for Good Clinical Practice (GCP): “Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).”
 - i. Documentation of GCP training will be maintained for all NETT personnel (including Contract Research Associates) throughout their employment.
 1. Acceptable documentation includes training programs endorsed and accepted by DHHS or its agents
 2. Documentation will be provided by each site for each participating research staff member
 3. Copies of the documentation will be uploaded and maintained in WebDCU™
 - b. Protocol specific and protocol related training is required of all study staff participating in the conduct of a NETT trial.
 - i. Documentation of protocol-specific training will be documented in the following ways:
 1. Attendees of protocol specific training meetings will be verified and included within the meeting summary or minutes. The summary or meeting will serve as the documentation of training.
 2. Study staff who do not attend protocol specific training meetings will undergo training either online or at the site as appropriate
 3. Study staff training at the site will be documented by the person(s) providing the training in a visit report or a summary document as appropriate.

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4. Verification of trainings for all study personnel will be entered into WebDCU™
 - c. Documentation of training for project monitoring staff
 - i. The organization providing monitoring expertise will provide the NETT CCC with a copy of the SOPs for training and certification of monitoring staff within their organization.
 - ii. Documentation project monitor orientation and training must be to the NETT CCC by the appropriate organization prior to commencement of monitoring activities.
 - iii. Project monitoring personnel are responsible for completing ongoing training as required per their role in the NETT network.
2. Approval for Process Exemption
 - a. The Director of Site Operations or designee must approve exemption from the processes outlined in sections two and three of this policy. The Director of Site Operations or designee must maintain documentation of the exemption approval.

Procedure Author

NETT Network Operations Committee, NETT CCC

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