

PI Attestation of ESETT Re-Training

Required:

When no subjects have been enrolled within a 6 month period (per the NETT SOP), retraining requirements are to be completed by the 6 month milestone.

Re-Training Requirements Include:

- 1) All study team members listed on the DOA (Delegation of Authority) log are required to review the following: the current protocol training video OR protocol training slide set.
- 2) Clinical team in-services for clinical site staff likely to be involved in enrollment and/or identifying subjects.
- 3) Study team members with CRF completion/data entry responsibilities are required to review the Data Training video or CRF Guidelines document.
- 4) Review Pharmacy Data Training with study pharmacists.
- 5) If supplied, ensure that the Protocol Assist Device(s) (PAD) are fully charged and connects to internet.
- 5) Maintain Regulatory Compliance.
- 6) Considerations will be made for spokes with study team overlap within the Hub-Spoke Complex.
- 7) The PI Attestation affirming that the retraining activities at the institution have been completed (via signature on the attestation document, uploaded as: Hub PI Attestation of Re-Training).

NOTE: Individual team member attestations are not required to be uploaded. The PI attestation of training will serve as documentation that all of the above requirements have been met by the study team.

The signature below is an attestation for completion of the above-mentioned requirements:

PI: _____ Date: _____

Name of Retraining Spoke/Site: _____