

PI Attestation of SHINE and ISPOT Re-Training

Required:

When no subjects have been enrolled within a 6-month period (per the NETT SOP).

Re-Training Requirements Include:

- 1) All study team members listed on the DOA (Delegation of Authority) log will be required to review the following: the current SHINE protocol and MOP OR the recruitment quiz, protocol adherence quiz and updated FAQs for SHINE.
- 2) Nursing in-services for clinical site staff likely to interact with subjects. (OR) Draft a just-in-time nursing training plan in lieu of in-services.
- 3) The study team will be required to review the SHINE Data/Randomization Training appropriate to their role.
- 4) For sites participating in ancillary ISPOT study, review ISPOT blood collection and processing procedures. Check ISPOT kits to ensure kits are complete with blue top tubes. Check expiration dates for blue tops.
- 5) Log in to study laptop to ensure its working appropriately and connecting to internet.
- 6) Maintain Regulatory Compliance.
- 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).
- 8) Considerations will be made for spokes with study team overlap within the Hub-Spoke Complex.

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: _____