

## PI Attestation of HOBIT Re-Training

Required:

When no subjects have been enrolled within a 6-month period (per the SIREN 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:
  - a) review the current Protocol Training Video **OR** Protocol Training Slide Set
- 2) Clinical team in-service for clinical site staff likely to be involved in treating subjects
- 3) Study team members with CRF completion/data entry responsibilities are required to review the Data Training Video **OR** CRF Guidelines Document
- 4) Blinded GOS-E Assessors must review the GOS-E training and example videos
- 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: PI Attestation of Re-Training)

NOTE: Individual team members' attestation 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 \_\_\_\_\_