End of Study Regulatory Compliance

Established
Status
Epilepticus
Treatment
Trial

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Ongoing Responsibilities for Active Sites

- It is the responsibility of each Hub/Site to maintain regulatory compliance
- Site documents and people documents must be kept current in the ESETT Database
- Study team personnel whose regulatory compliance lapses cannot participate in trial related activities

During PD Activities

- Spokes

Applies to: All Spokes who enrolled 1 or more ESETT subjects.

  - FWA
  - Current IRB Approval (version 2 of protocol)
  - FDA Form 1572
  - Electronic Delegation of Authority (eDOA) Log

- People

Applies to: At minimum, the Hub PI, Trial PI and Primary Study Coordinator; any other team members participating in PD Activities.

  - CV
  - Medical License
  - HSP Certification
  - GCP Certification

Post-PD Activities

- Inform IRB of final study close out following conclusion of PD events.
- Upload documentation from the IRB regarding final study closure once PD events have conlcuded in WebDCU under: IRB Close-out Acknowledgement.
- Update the eDOA log to reflect end of study: Add end dates for all active team members to correspond with IRB closure of the trial.
- Maintain regulatory compliance in WebDCU until above items are completed.

Questions?

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