End of Study Regulatory Compliance

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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 concluded 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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