Ongoing Regulatory Maintenance

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Ongoing Responsibilities

• 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
Site Documents

- FWA
- CLIA
- Current IRB Approval (version 2 of protocol)
- IRB Approved Informed Consent, Assent Forms
- FDA Form 1572
- Attestation of Study Team Training
- Electronic Delegation of Authority (eDOA) Log
FDA Form 1572

• Should reflect roles and responsibilities on the eDOA.
• Includes those:
  • Responsible for the trial
  • Obtaining informed consent
  • Responsible for determining/reporting AE/SAE
• NETT Hub PI generally on their Spoke’s 1572
• Multiple sites can be listed on the same 1572
People Documents

• Requirements defined by eDOA
• All: CV, HSP, HIPAA, Protocol Training
• As needed: Medical License, ESETT Data Training, Regulatory Database Training, Sample Handling and Shipping Certification.
• Pharmacist: Pharmacy Data Training and License.
Things that get people in trouble

• Annual Scheduled Continuing Renewals
  • Application and Approval

• Change in PI, Study Team Members
  • eDOA, IRB approval, and 1572
Retraining Requirement

• Per NETT SOP, with absence of recruitment in a 6 month period, retraining is required
  • Study Team
  • Clinical Staff
  • Pharmacy Staff

• Method of retraining can be determined locally, so long as it reaches these populations

• Documented by PI Attestation of Retraining in the ESETT Database