Ongoing Regulatory Maintenance

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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
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 and PM should be on their Spoke’s 1572
• Multiple sites can be listed on the same 1572
People Documents

• Requirements defined by eDOA
• All: CV, HSP, Protocol Training
• As needed: Medical License, ESETT Data Training, Regulatory Database Training, Sample Handling and Shipping Certification
• Pharmacist: Pharmacy Data Training and License
• No longer collecting HIPAA!
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
Sites Closed to Enrollment

- Remain current with IRB
- Update 1572 and DOA log
  - Remove team members no longer participating
  - PI and Primary Study Coordinator need to remain active
- Maintain regulatory compliance for site and active team members
- EFIC PD activities
  - Not required at this time
  - Will be required after the publication of the primary paper
  - CCC will provide template materials
Study Drug Destruction

• Adult only sites (closed to enrollment)
  • All study drug vials can now be destroyed
  • Update the Drug Removing from Inventory table, select

• Adult and children sites (open to enrollment)
  • Adult and Elder study drug vials can now be destroyed
  • Update the Drug Removing from Inventory table, select
  • Retain child and back up vials in refrigerated storage for use
PADs and Use Next Boxes

• Adult only sites (closed to enrollment)
  • Return all boxes, with attached PADs, to CCC
  • To request shipping labels, please contact Lindsey Harris (liha@med.umich.edu)

• Adult and children sites (open to enrollment)
  • Return adult and elder boxes, with attached PADs, to CCC
  • Retain child use next boxes for use
  • To request shipping labels, please contact Lindsey Harris (liha@med.umich.edu)
Site Management Questions

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