# Ongoing Regulatory Maintenance

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**E**pilepticus
**T**reatment
**T**rial

Erin Bengelink

# 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

- Erin Benelink – ezajaros@med.umich.edu
- Natalie Fisher – brownnat@med.umich.edu

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