Ongoing Regulatory Maintenance

Established
Status
Epilepticus
Treatment
Trial

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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

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