PEM Research Assistant Training Binder

Tab 1: General Research Consent Requirements (site specific)

Tab 2: Flow-chart for enrolling patients

Tab 3: Most UTD copy of consent and HIPAA

Tab 4: Copy of all surveys (English and Spanish)

Tab 5: Consent note to be placed in MR (site specific) and how to find smart phrase

Tab 6: Source document for bedside 20 and 60 minute assessments

Tab 7: ESETT Protocol Assist Device Instructions

Tab 8: ESETT Protocol and MOP

Flow-chart for enrolling patient for ESETT

1. You get notified (either pager if you're at home) or during your shift in the ED
    a. If paged, call number back ASAP and let the pharmacist know that you're on your way and make sure there are no difficulties (patient isn't having allergic reaction, blood glucose was checked prior to enrollment, unblinding isn't required, etc.)

2. During 60 minute primary outcome, you're on standby. Make sure you're available to answer any questions, monitor that the study drug is being administered over 10 minutes, and that the pharmacy staff is answering source document.
    a. Call hotline (1-855-373-8874) only if emergently needed to unblind before the 60 minute mark. If at/after the 60 minute mark, we can unblind using the iPod.

3. At the 60 minute mark, please unblind using the iPod.
    a. The iPod will ask the last few questions (same as on the source document) and once those are answered a screen will pop up asking if we want to unblind.
    b. Please click "yes" and make sure to note the study drug given and the time you unblinded.
    c. At 60 minutes it is no longer considered emergency blinding so it's fine to do so. Of course if the attending needs to unblind emergently, we can always call the study hotline within the first 60 minutes and get it unblinded.
    d. Send data from iPod to study site.

4. Then get consent. Call translation if needed (ask HUC or nurse to order translation in EPIC). Get translator's name and ID for EPIC note.

    a. Consent Requirements:
        i. Go over:
            1. Study Purpose
            2. Study Procedures/Length of Time
            3. Study Risks/Benefits
            4. That participation is voluntary
            5. What the alternatives to participation are (if any)
        ii. Parents must print, sign, date, and time the consent form
        iii. Patients 10-17 will sign, date, and time the consent form (have them date/time themselves)
            1. If sick/unable to sign→can still enroll→make a note in EPIC AND underneath signature line on consent form
        iv. We print, sign, date/time consent form when obtaining consent
    b. Make copies (2 copies of consent, 1 copy of HIPAA)
        i. Family receives 1 copy of consent and 1 copy of HIPAA.
        ii. Medical Records should receive 1 copy of consent.
    c. Put consent note in EPIC and fill in all necessary blanks

i. Research Consent Note: Found under .ESETTRESEARCH in Progress Notes
    1. Be sure to complete all blanks highlighted by the smart text including: name of person authorizing consent, relationship to patient, if assent was obtained (if not, please explain why), time/date of consent, who obtained consent, and if a translator was used.
    2. At the bottom of the note, please include the total dose in **mg,** what the study medication was (determined after unblinding), and the time of unblinding.
        a. Use the colored source document (what the pharmacists fill out at bedside) to write the total infusion volume (mL).
        b. On colored source document (what pharmacists fill out at bedside) there is a line where they write the total infusion volume (this is in mLs).
        c. Multiply this number by the concentration of the study drug:
            i. Fosphenytoin=16.66mg/mL
            ii. Valproate=33.33mg/mL
            iii. Levetiracetam=50mg/mL
        d. This will give you total dose in mg. ***Please verify this number with pharmacy!! Do not confuse the volume (in mLs) and concentration (mg/mL) with the dose (mg).***

5. Give family survey and collect when done. If they haven't finished the survey or don't wish to do it, that's fine, just send the Research Coordinator a quick email letting them know.

6. Help pharmacist restock use next box and make sure iPod is loaded with the scans from both the new study drug vial and WebDCU.
    a. Scan vial of new study drug
    b. Scan WebDCU on computer – ("Drug Tracking"→"Drug Received")
    c. Place a new source document (in filing cabinet) into ESETT Use Next Box.
    d. Close box/give back to pharmacist to put in Omnicell.
    e. Check ESETT Study Drive (→Enrollment Log) to make sure patient isn't already enrolled previously
7. To randomize-WebDCU→Add New Subject and Complete Form.
    a. Can then go to Subject CRF Binder in WebDCU to view.
8. Please hand out candy goodie bags (if you can) after the enrollments. Don't do it in front of patients/families, but rather just try to get it to the individual by placing it on their keyboard/desk area. We typically give a goodie bag to the attending, resident, fellow, nurse who administered the study drug and pharmacist.

9. Research Visit Note: Found under .ESETTVISIT in Progress Notes
    a. Completed after the patient has been discharged from the hospital (will most likely not be the same day of admission).