**ESETT Readiness Checklist  
Call in:** **1-866-842-5779** / **Access Code:** **395 061 7438**

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| --- | --- |
| HUB/PECARN NODE |  |
| SPOKE/SITE |  |
| DATE OF READINESS CALL |  |
| SITE PARTICIPANTS | Site PI:  Site Primary Study Coordinator:  Pharmacy Representative(s):  Hub PI:  Hub PM:  Other Team Members: |
| ESETT & NETT PARTICIPANTS | (For CCC Use)  ESETT PI(s):  NETT CCC Staff:  MUSC Staff:  Other: |

**PEOPLE DOCUMENTS *(Check if complete. If incomplete, please explain.)***

CVs (PIs, Co-Is, Primary Study Coordinators, Pharmacy Contact, Secondary Study Coordinators)

Medical License (PIs, Co-Is, Primary Study Coordinators, Pharmacy Contact, Secondary Study Coordinators)

HIPAA (PIs, Co-Is, Primary Study Coordinators, Secondary Study Coordinators)

Human Subjects Protection (PIs, Co-Is, Primary Study Coordinators, Secondary Study Coordinators)

Protocol Training (PIs, Co-Is, Primary Study Coordinators, Secondary Study Coordinators)

Data Training (Primary Study Coordinators, Secondary Study Coordinators)

Pharmacy Data Training (Study Drug Recipients\*)

Good Clinical Practice Training (PI, Co-Is, PSC, SSC, and other team members with study oversight resp.\*)

Sample Handling and Shipping and Handling Certification (Primary and Secondary Study Coordinators)

**SPOKE DOCUMENTS**

FWA

CLIA Certification

HSP and HIPAA Policy

Electronic Delegation of Authority Log accepted by CCC is current for full study team list

FDA Form 1572

Documentation of EFIC Plan Submittal

Approval of EFIC Plan

Full Study IRB Application Submittal for ESETT V1

IRB Approval for Protocol V2

IRB Approved Informed Consent Forms (includes survey language) Protocol V1

IRB Approved Non-English Consent/Assent Forms (if applicable)

IRB Approval of Notification Letter to LAR

IRB Study Communication (if applicable)

**ESETT TRAINING**

Clinic staff on key units trained in study procedures (PI Attestation of Study Team Training)

**EFIC CC and PD**

CC forms completed for all CC activities to date

PD forms completed for all PD activities to date

**STUDY LOGISTICS**

***Please consider each of the questions listed below.  Using this document as a template, please enter a text response to each item. The completed document will serve as a summary of how you will be conducting the trial at your site.***

***If there are differences in how adults and pediatrics will be handled at your site, please differentiate these in your answers.***

**Human Subjects Protection/EFIC (CC/PD)**

1. What was your single best experience conducting EFIC activities for ESETT?
2. Does your IRB-approved EFIC plan include ongoing PD activities?

**Enrollment**

1. How will potential ESETT patients be identified in your ED?
2. Where will the Use-Next box be kept refrigerated and who will retrieve it?
3. Describe your study team on call coverage? (Who takes call? How are they activated? What are your expected response times? How do you ensure 24/7 coverage or what contingencies exist for gaps in coverage?)
4. Describe how you expect the study team to interact with the clinical team in the ED. How will subjects be followed after the enrollment? Who on the study team will be responsible for the 24 hour and ongoing S/AE assessments?
5. How will the study box be returned if the study team arrives late?
6. What is your expected need or procedure for un-blinding, if desired?
7. How will your study team be notified of an enrollment (as a back-up to the PAD)?

**Consent**

1. Describe your process for identifying LAR, documenting these efforts in WebDCU, and then notifying and obtaining informed consent. Have you had requests to opt out and, if so, how many and how do you handle these?
2. There is also an expectation to have subjects (surrogates) complete the attitudes survey, even if they refuse ongoing participating in ESETT, per the Study Withdrawal Addendum, which needs to be included. How are you implementing the brief “Attitudes toward enrollment survey?”

**Pharmacy**

1. How will the study team and pharmacy share Use-Next box responsibility? (Whose responsibility it is to set up the backup/replacement vial? Who will recharge device and what is the planned frequency of recharging, etc.)
2. Describe the process for re-setting and reloading the Use-Next box after an enrollment at your site? (Where will the Back-up Vial be stored? Whose responsibility is it to replace with back up vial? When after an enrollment will this be done? What process do you have to let the pharmacy know when a subject has been enrolled?)
3. Provide the Primary Study Drug Recipient’s name, full address where study drug will be shipped, and shipping phone number below. Update this information within the Clinical Site table in WebDCU (under site management tab) (During the readiness call, site will verbally confirm by reading aloud the address and phone number)
4. Please confirm that the primary and secondary pharmacists have access to the WebDCU database?

**Training**

1. Detail which team members were able to be at the investigator meeting in Sept 2015 in Detroit. Was the PI and/or Primary Study Coordinator present at that meeting?
2. Describe initial and ongoing planned training of physicians, nurses, social work, and pharmacists at your site.
3. Describe the training of other study team members and training materials - e.g., videos from the ESETT investigator meeting available on the study website, read the protocol, watched enrollment and other training videos, etc.

**Other logistics**

1. Have you confirmed iPod internet accessibility in the ED?
2. Describe your process for drawing, processing, storing and shipping the blood samples.
3. Do you expect to have competing trials (either trials that compete for subjects or other trials that might compete for the attention of the research coordinators during a potential enrollment)? If so what management strategies will you use?
4. Has your site received the Use Next box(es), protocol assist device(s), and pocket cards?

1. Who are the team members who will be notified when the PAD is turned on (please list)? Have their email/phone numbers been provided to the CCC ESETT Team? Have you tested the PAD to check that these team members receive the notification?

1. Who would be the primary point of contact for questions re: ESETT protocol questions in the absence of a study team member at enrollment?

**Remote Source Document Verification Monitoring**

1. What is your prior experience with remote monitoring at your site? Discuss your process and timeline to arrange for ESETT monitor access to the electronic health record.

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| **ACTIONS REQUIRED PRIOR TO START-UP** | |
| **Action** | **Date Completed** |
| **1.** |  |
| **2.** |  |
| **3.** |  |

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| --- | --- |
| **SITE ACTIVATION** | |
| **DATE  APPROVED FOR ACTIVATION** |  |
| **MUSC NOTIFIED?** |  |
| **STATUS CHANGED IN WebDCU?** |  |