

# PROTOCOL ASSIST DEVICE

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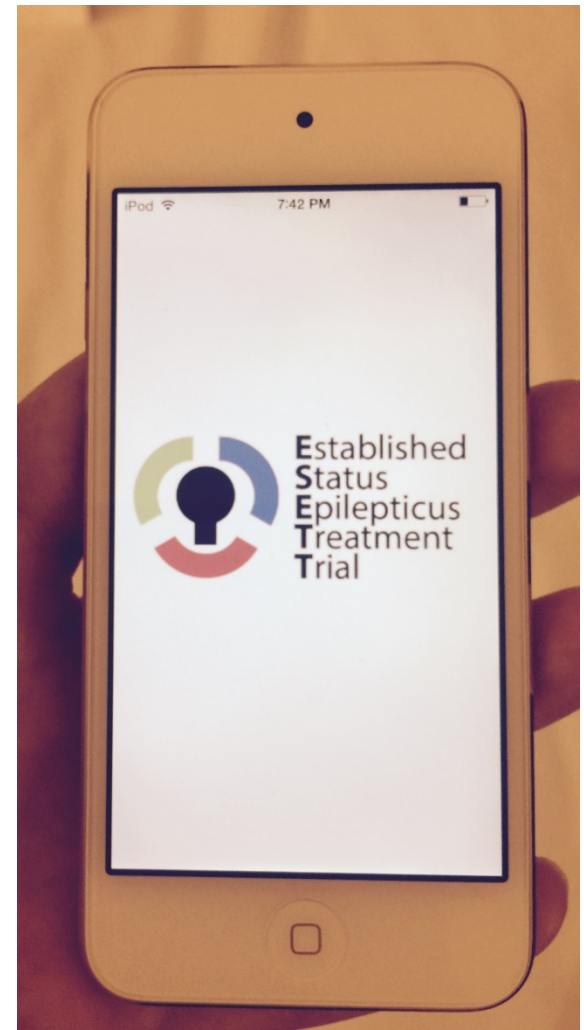
Amy Fansler, MPH

University of Virginia

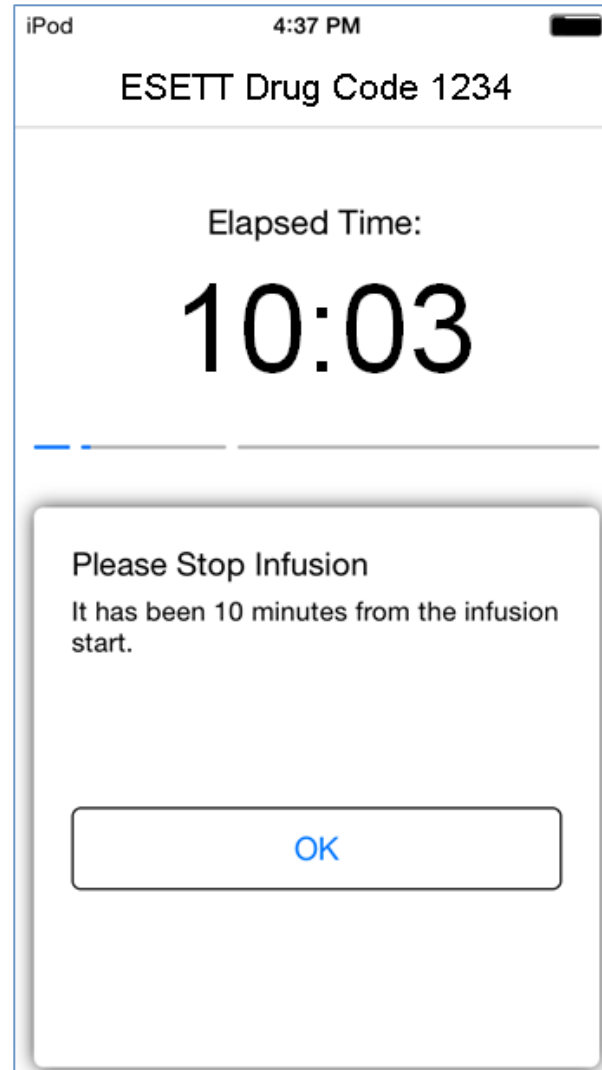
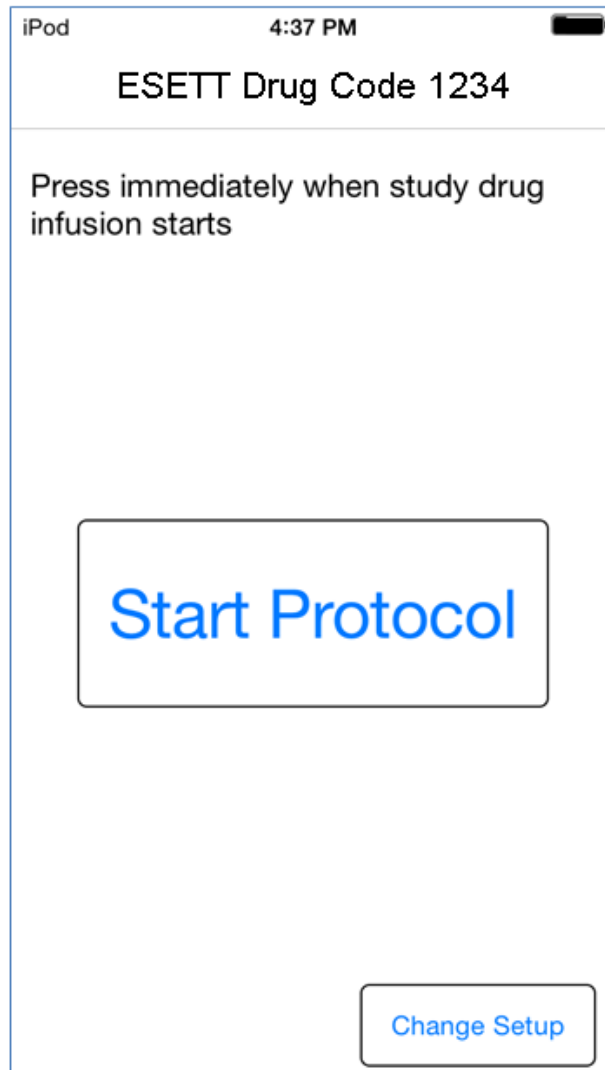


# Key Features

- Option to unblind when clinically necessary
- Infusion timing
- Prompts at 20 and 60 minutes
- Notification of study team member
- Audio recording and back-up source documentation



# Infusion Timing



# Assessments – 20 and 60 Minutes

iPod 4:38 PM

ESETT Drug Code 1234

Elapsed Time:

## 20:01

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**20 Minutes**

Please answer the following questions at 20 minutes from the infusion start.

Were there clinically apparent seizures?

Yes  No  Unknown

Was responsiveness to verbal commands or noxious stimuli improved

Yes  No  Unknown

[Submit Answers](#)

iPod 4:39 PM

ESETT Drug Code 1234

Elapsed Time:

## 60:11

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**60 Minutes**

Please answer the following questions at 60 minutes from the infusion start.

Were there clinically apparent seizures?

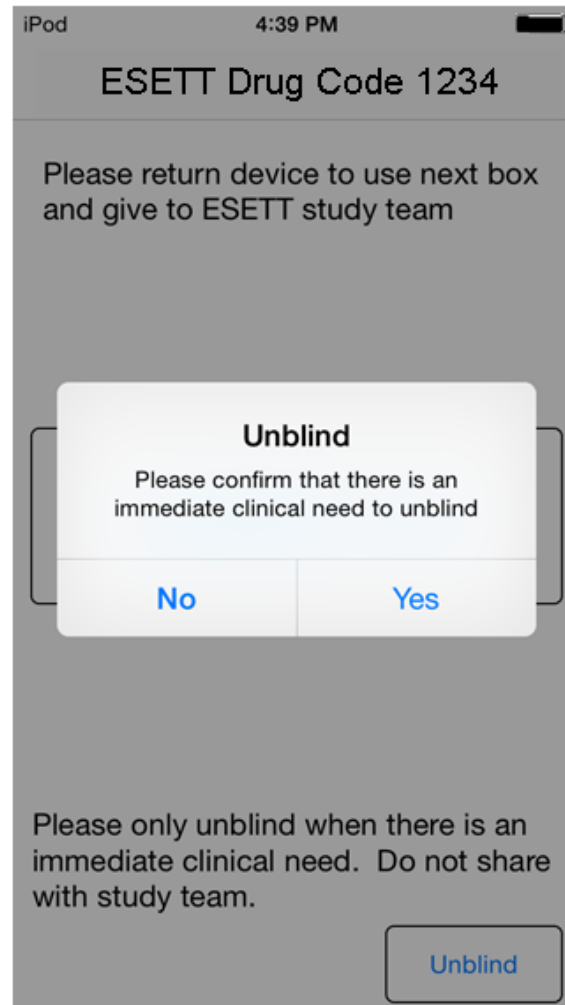
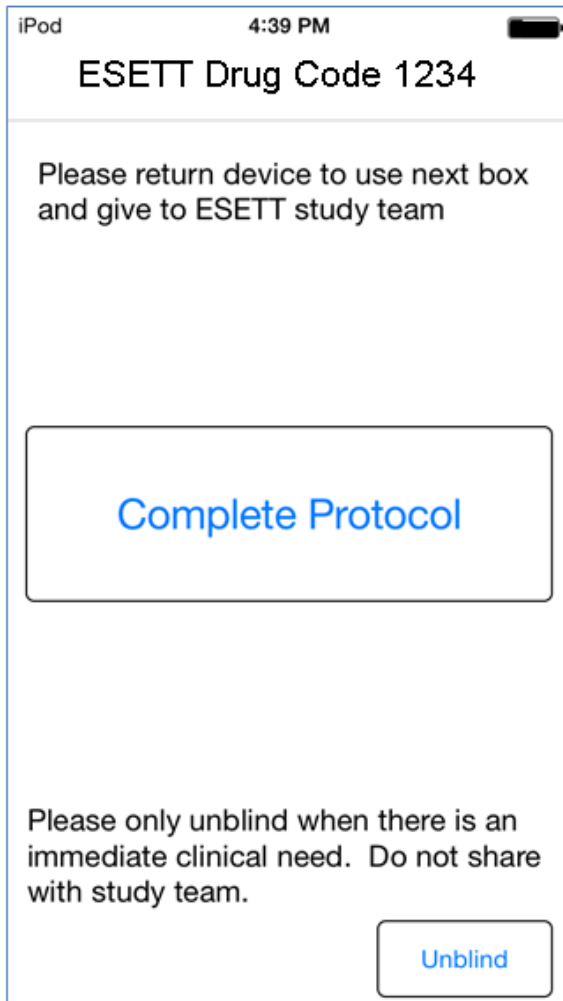
Yes  No  Unknown

Was responsiveness to verbal commands or noxious stimuli improved

Yes  No  Unknown

[Submit Answers and Finalize](#)

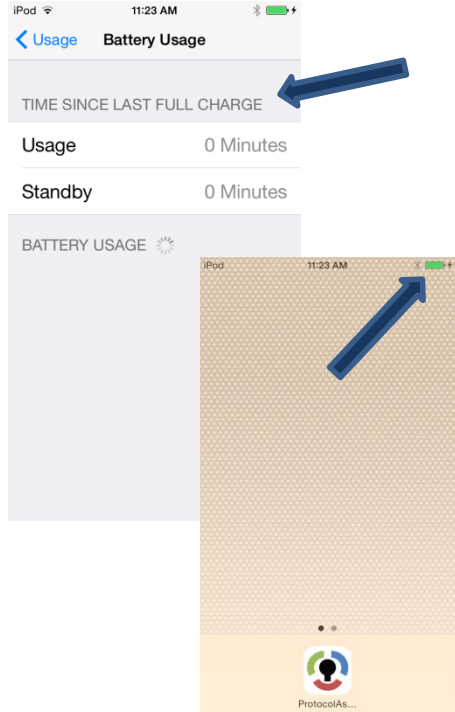
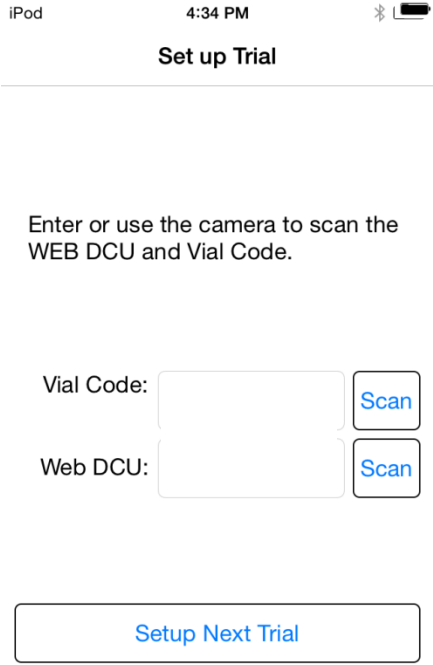
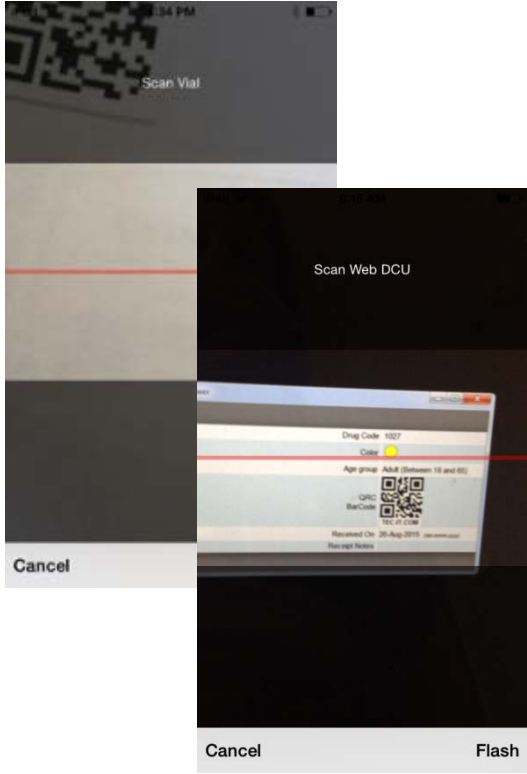
# Routine Unblinding



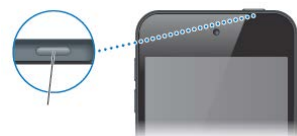
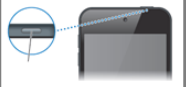



# DEVICE SET UP

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# Protocol Assist Device Set-Up

 <p>iPod 11:23 AM</p> <p>Usage Battery Usage</p> <p>TIME SINCE LAST FULL CHARGE</p> <p>Usage 0 Minutes</p> <p>Standby 0 Minutes</p> <p>BATTERY USAGE</p> <p>ProtocolAs...</p>	 <p>iPod 4:34 PM</p> <p>Set up Trial</p> <p>Enter or use the camera to scan the WEB DCU and Vial Code.</p> <p>Vial Code: <input type="text"/> Scan</p> <p>Web DCU: <input type="text"/> Scan</p> <p>Setup Next Trial</p>	 <p>Scan Vial</p> <p>Scan Web DCU</p> <p>Drug Code 1027</p> <p>Color</p> <p>Age group Adult (Between 18 and 65)</p> <p>QR Code</p> <p>Bar Code</p> <p>Received On 20-Aug-2015</p> <p>Cancel Flash</p>
<p>Confirm device is fully charged</p>	<p>Select Set Up</p>	<p>Scan barcode on vial and in WebDCU™</p>

# Protocol Assist Device Set-Up

<div data-bbox="171 425 388 634" data-label="Image"> </div> <div data-bbox="409 462 614 562" data-label="Text"> <p><b>Pediatric</b> 2yr to <math>\leq 17</math></p> </div> <div data-bbox="171 662 388 871" data-label="Image"> </div> <div data-bbox="421 691 656 848" data-label="Text"> <p><b>Younger Adults</b> 18yr to <math>\leq 65</math>yr</p> </div> <div data-bbox="171 922 388 1130" data-label="Image"> </div> <div data-bbox="423 948 651 1105" data-label="Text"> <p><b>Older Adults</b> 65yr or older</p> </div>	<div data-bbox="751 376 1205 1169" data-label="Form"> <p>iPod 8:13 AM</p> <p><a href="#">Back</a></p> <p><a href="#">Set up Trial</a></p> <p><b>Update Site Contact Information</b></p> <p>This is the contact that will be notified when a trial is started.</p> <p>Contact Name: <input type="text" value="Rosen Mann"/></p> <p>Contact Mobile Number: <input type="text" value="4345312930"/></p> <p>Contact Email: <input type="text" value="rosen.mann@..."/></p> <p><a href="#">Save Contact Info</a></p> </div>	<div data-bbox="1286 405 1823 1182" data-label="Complex-Block">  <div data-bbox="1450 539 1823 1182"> <p><b>HOW TO START PROTOCOL ASSIST DEVICE</b></p> <p>Established Status Epilepticus Treatment Trial</p> <ol style="list-style-type: none"> <li>Press and hold the Sleep/Wake button for ~10 seconds. </li> <li>Touch ESETT icon. </li> <li>Select 'Start Protocol' when infusion is started. </li> <li>Plug in device if needed. </li> </ol> </div> </div>
<p>Confirm color coding (WebDCU, vial, device)</p>	<p>Add study team member contact info</p>	<p><b><u>Power down device</u></b> and place with instructions in use next box</p>



# Other Device-Related Considerations

- Data transfer and reset
- What happens when it doesn't work?
- Routine checks and updates
- How will sites receive?



**Established  
Status  
Epilepticus  
Treatment  
Trial**