PROTOCOL ASSIST DEVICE

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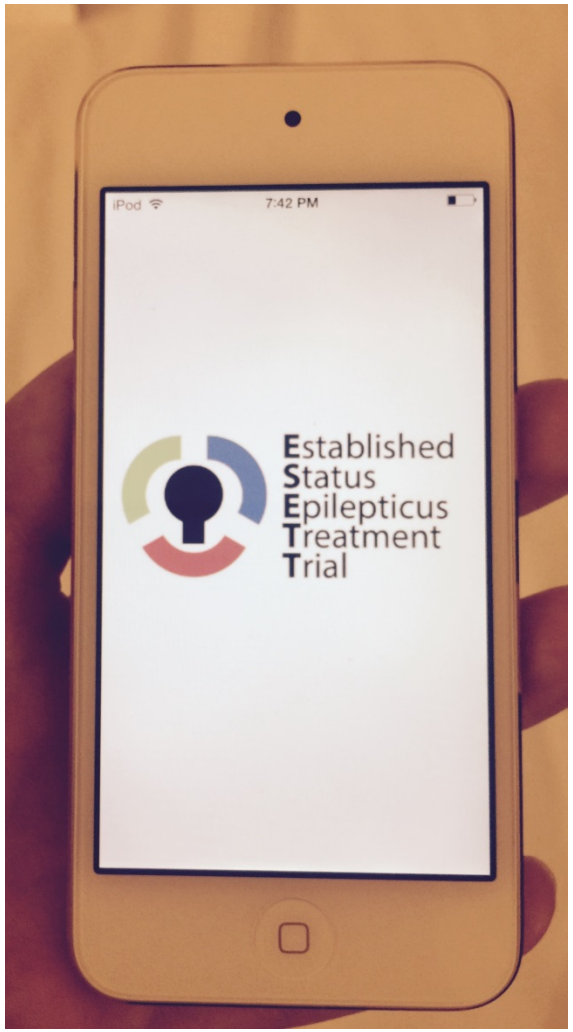
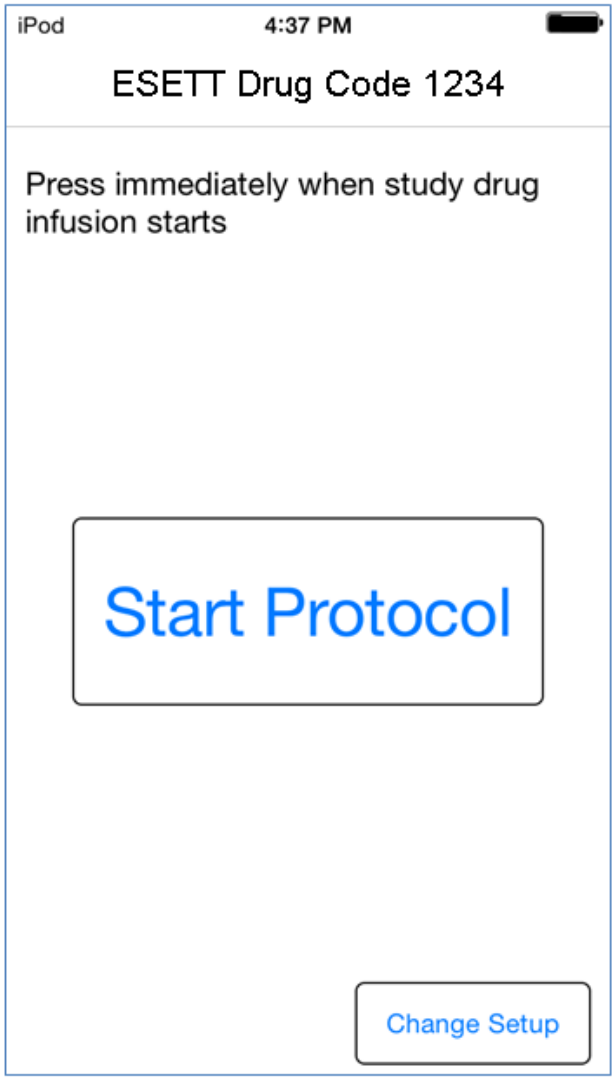
Established Status Epilepticus Treatment Trial

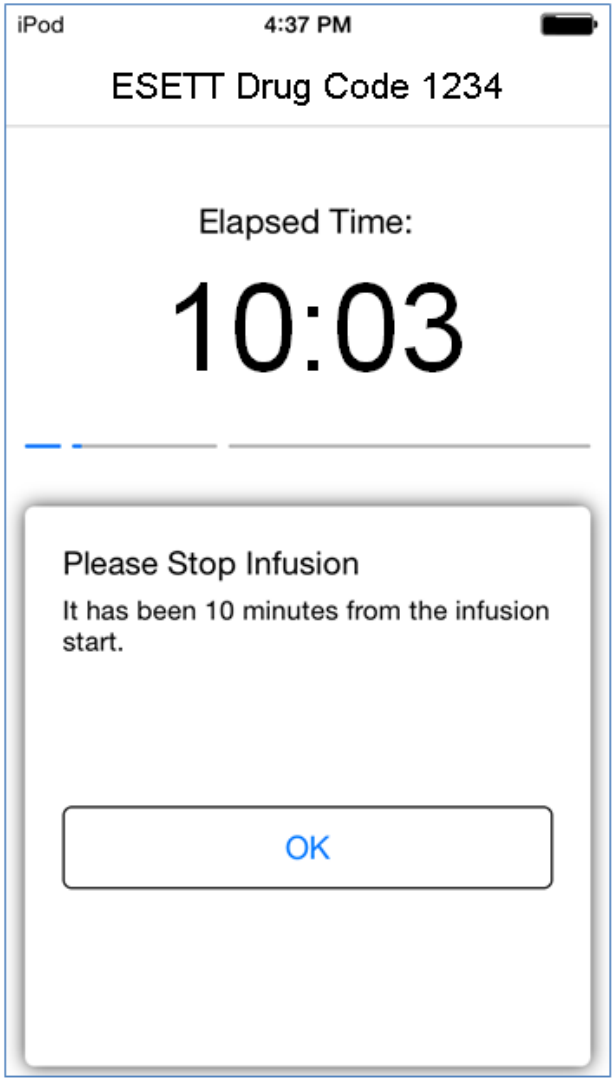
Key Features

- 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





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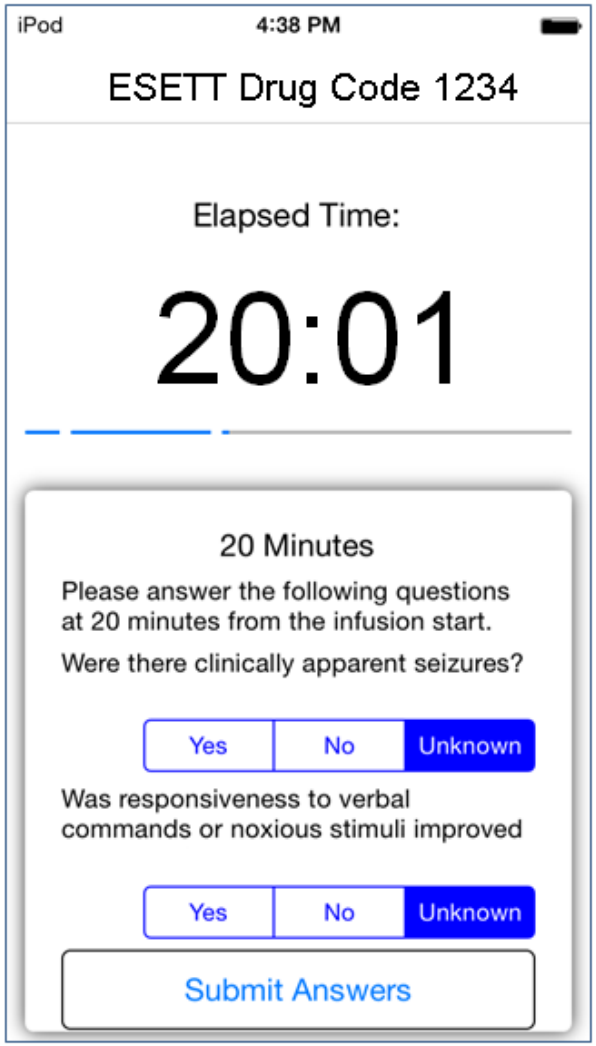
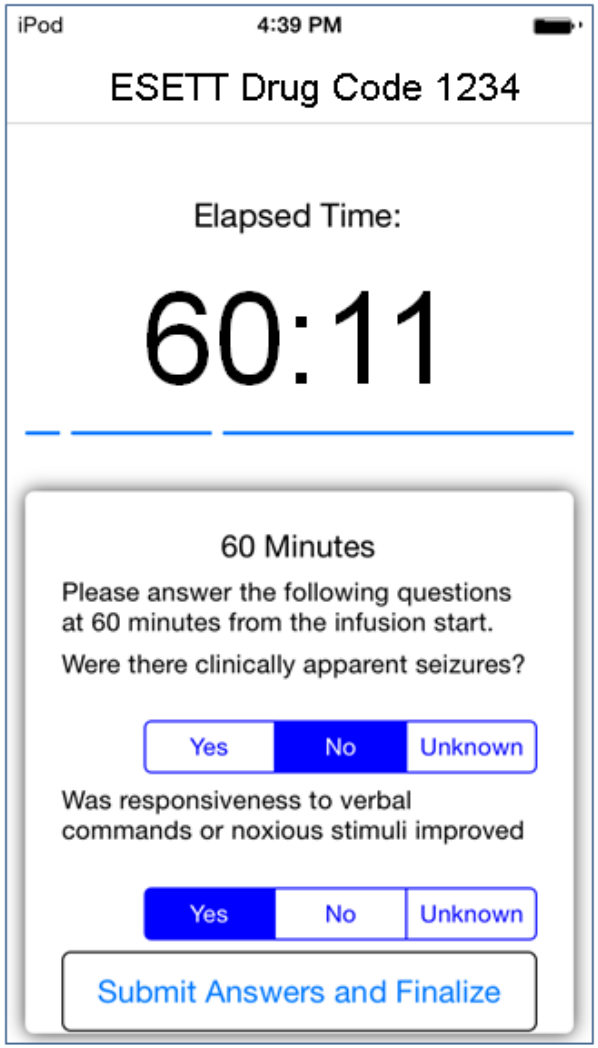
Assessments – 20 and 60 Minutes





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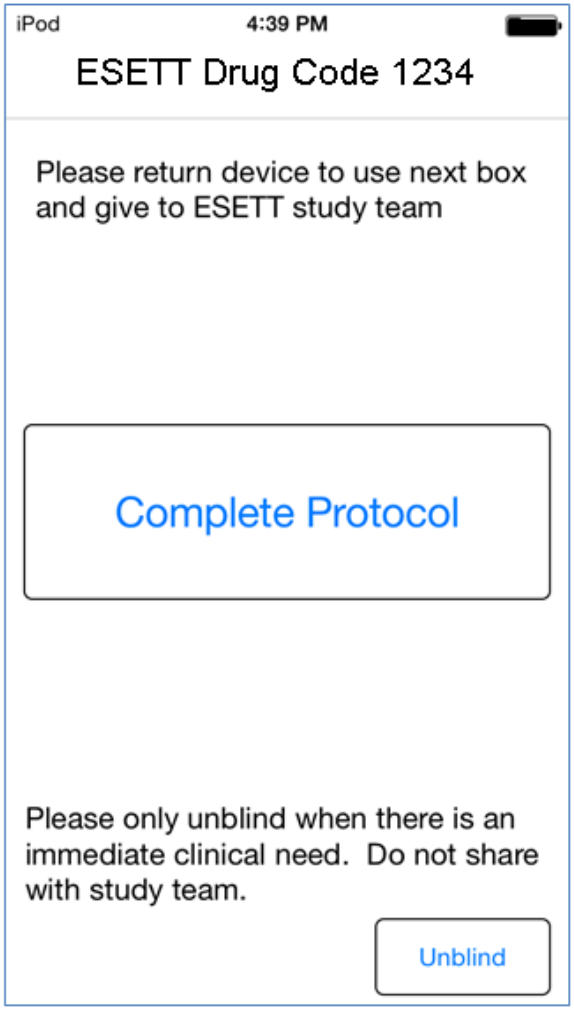
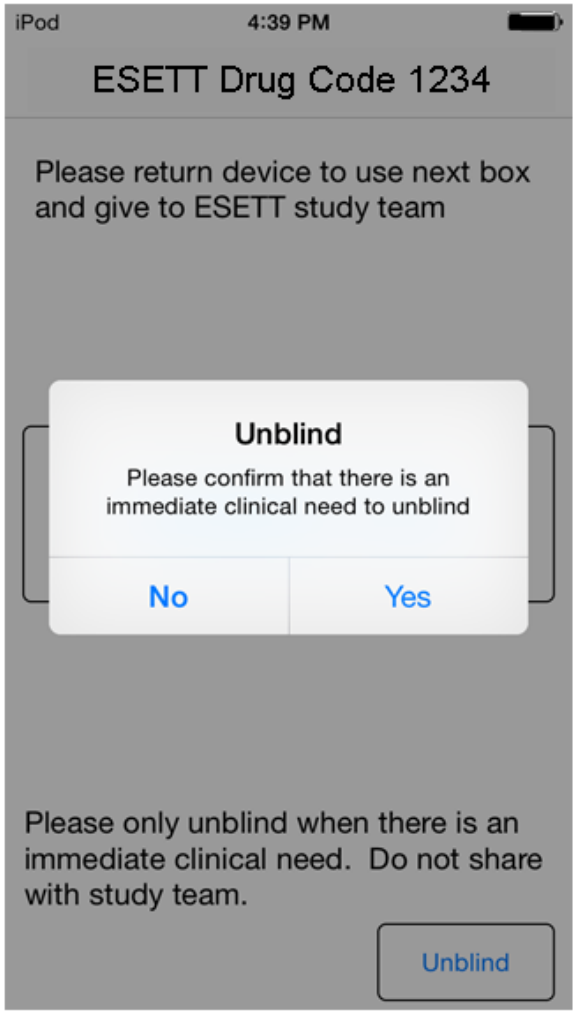
Routine Unblinding





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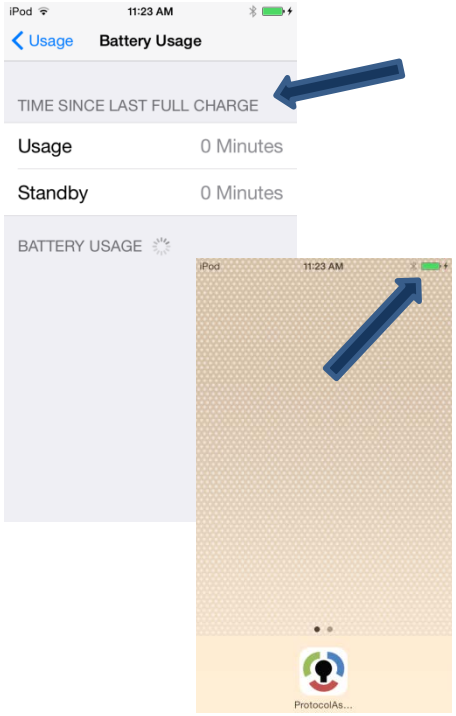
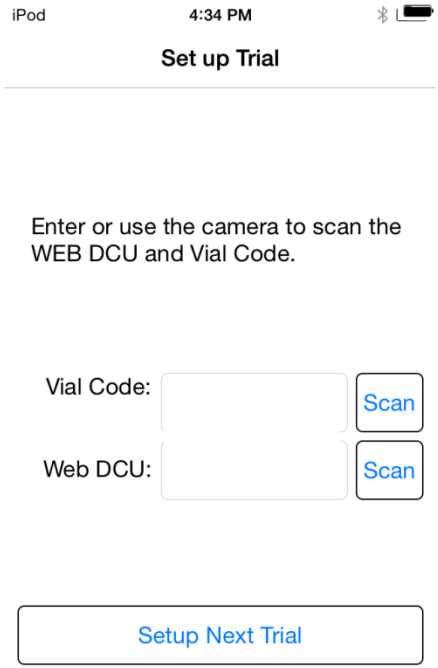
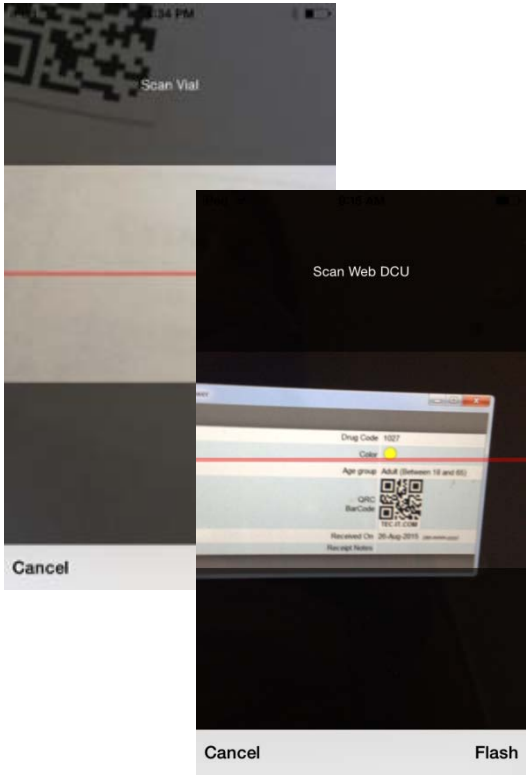
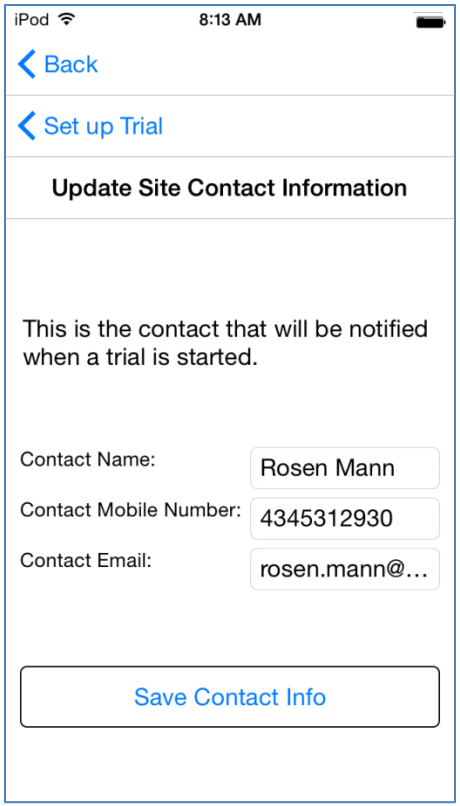
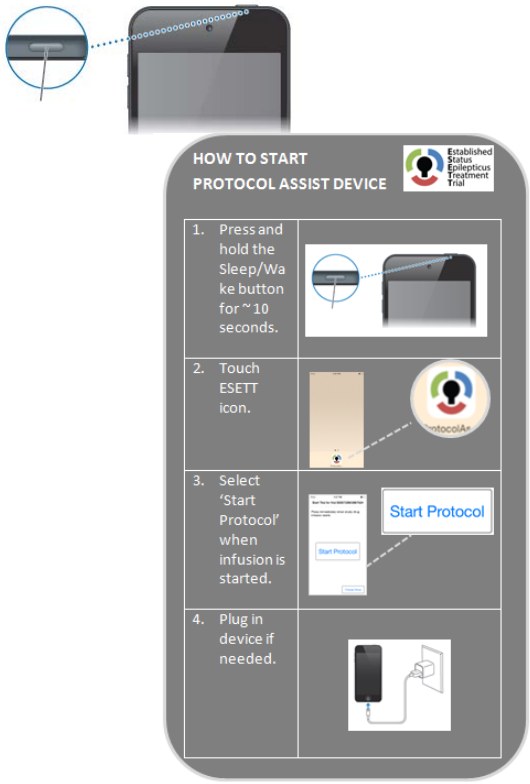
DEVICE SET UP

Protocol Assist Device Set-Up

		
Confirm device is fully charged	Select Set Up	Scan barcode on vial and in WebDCU™

Protocol Assist Device Set-Up

Pediatric 2yr to ≤17 Younger Adults 18yr to ≤65yr Older Adults 65yr or older		
Confirm color coding (WebDCU, vial, device)	Add study team member contact info	**Power down device** and place with instructions in use next box

Other Device-Related Considerations

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

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