# KESETT All Site Call 7/25/2025

# Agenda

00. Welcome

Jaideep Kapur

01. Tasks and Timeline

Vincent Cervantes

CCC

02. Enrollment Overview

Robert Silbergleit

CCC

03. WebDCU v2

Riley Luckman

DCC

04. Reporting EFIC Activity

Erin Bengelink

CCC

05. EFIC Core

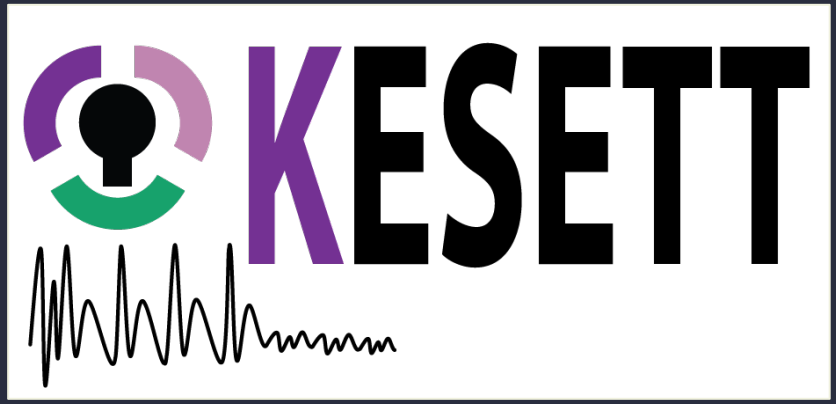
Shannon Stephens

UAB 10 min

06. **Ceribell & Study Drug**

Megan Wardius

UVA 10min




# Welcome:

## Jaideep Kapur, MD PHD

# Trial Progress

01. **FDA release of Clinical Hold**

02. **DSMB recommends proceeding**

03. **Central IRB Approval any minute**

04. **First milestones met ontime**

05. **Investigator Meeting - Oct. 16 & 17 (in-person)**

# MILESTONES 12/31/2025

30 sites released for enrollment

01. Contracts Executed
02. Local IRB Ceding Approval
03. EFIC Complete
04. IDS Pharmacy Trained
05. Ceribell approved and trained on
06. Readiness/activation call

**Site Start-up Payments – $20,000 Total (inclusive of F&A)**

Two (2) milestone payments totaling $20,000 (inclusive of F&A costs) will be paid in two (2) $10,000 increments to the first 60 leadership-approved KESETT sites that complete the following tasks.

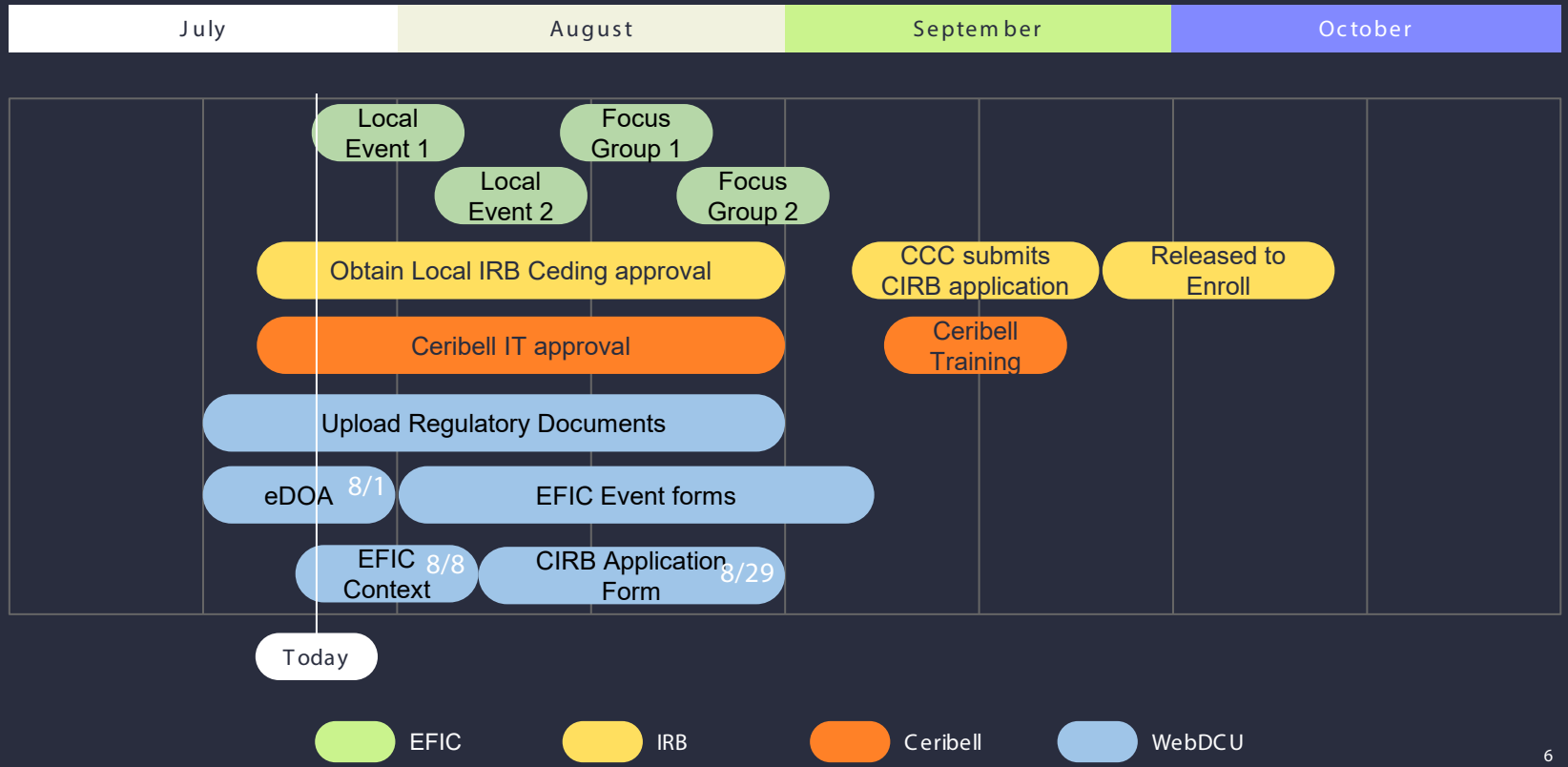
1. Submit your local IRB ceding approval letter. Upload to WebDCU to the regulatory document titled: **Ceding Acknowledgment from Local IRB.** CCC will mark this as accepted.
2. Complete the KESETT electronic delegation of authority (eDOA) log. The eDOA lists study members, their contact information, and their roles and responsibilities, including those involved in EFIC activities. CCC will mark this as accepted.
3. Complete Local Context Form (LCF) in WebDCU. The LCF includes information for the CIRB about your site, and information for UAB to build your website, social media campaigns and surveys. CCC will mark this as completed.
4. Complete an intake meeting with UAB. The intake meeting is the first step to UAB starting your website, social media campaigns and surveys. UAB will mark this as completed.
5. Report plans for two in-person community consultation events. Document event plans in WebDCU on the CC event form. CCC will mark this as completed.

| Milestone Payment 1 | Reads READY in WebDCU when tasks 1-5 are accepted or completed | $10,000 inclusive of F&A |
|---|---|---|

6. Site completes readiness/activation call and is open to enrollment in WebDCU.

| Milestone Payment 2 | Reads READY in WebDCU when tasks 6 is completed | $10,000 inclusive of F&A |
|---|---|---|

# Sample Site Timeline



# Enrollment Overview: Robert Silbergleit, MD

# Enrollment overview

- Eligibility
- Enrollment flow
- Starting intervention

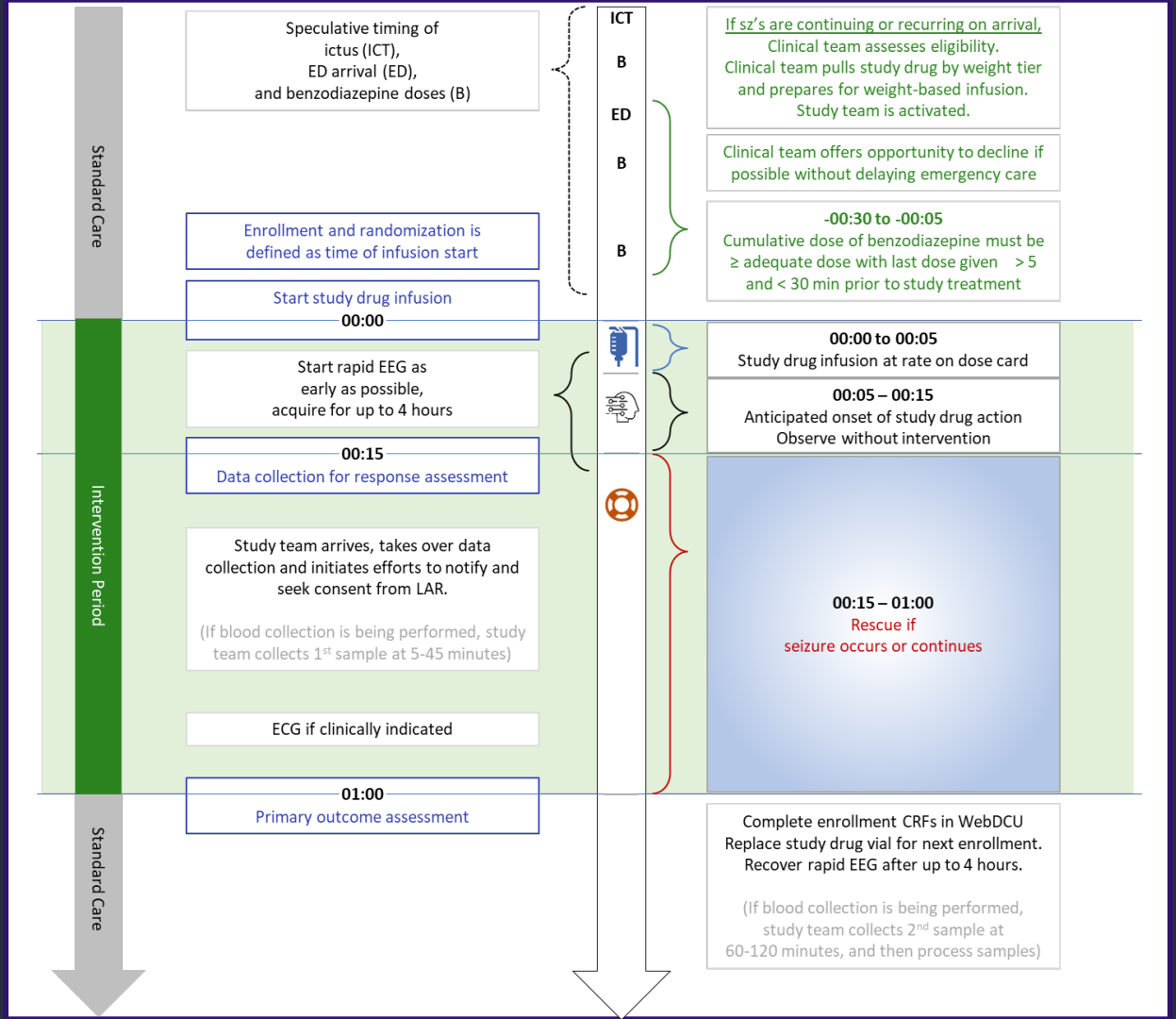
# Eligibility

## Inclusion

- Convulsive seizure > 5 minutes
- Seizures continue / recurring in ED
- Despite adequate dose of benzos
- Age ⩾ 1 year, est. wgt > 10kg

## Exclusion

- TBI, cardiac arrest, hypoglycemia
- Known allergy / contraindication to drugs or EEG
- Already recvd 2nd line agent
- Already recvd other anesthetic
- Already intubated
- Known pregnancy
- Prisoner
- Opt out identification


Standard Care
Intervention Period
Standard Care
Speculative timing of ictus (ICT), ED arrival (ED), and benzodiazepine doses (B)
Enrollment and randomization is defined as time of infusion start
Start study drug infusion
00:00
Start rapid EEG as early as possible, acquire for up to 4 hours
00:15
Data collection for response assessment
Study team arrives, takes over data collection and initiates efforts to notify and seek consent from LAR.
(If blood collection is being performed, study team collects 1st sample at 5-45 minutes)
ECG if clinically indicated
01:00
Primary outcome assessment
ICT
B
ED
B
B
If sz's are continuing or recurring on arrival,
Clinical team assesses eligibility.
Clinical team pulls study drug by weight tier and prepares for weight-based infusion.
Study team is activated.
Clinical team offers opportunity to decline if possible without delaying emergency care
-00:30 to -00:05
Cumulative dose of benzodiazepine must be ≥ adequate dose with last dose given > 5 and < 30 min prior to study treatment
00:00 to 00:05
Study drug infusion at rate on dose card
00:05 – 00:15
Anticipated onset of study drug action
Observe without intervention
00:15 – 01:00
Rescue if
seizure occurs or continues
Complete enrollment CRFs in WebDCU
Replace study drug vial for next enrollment.
Recover rapid EEG after up to 4 hours.
(If blood collection is being performed, study team collects 2nd sample at 60-120 minutes, and then process samples)

Standard Care

Speculative timing of
ictus (ICT),
ED arrival (ED),
and benzodiazepine doses (B)

ICT

B

ED

B

B

If sz's are continuing or recurring on arrival,
Clinical team assesses eligibility.
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Start study drug infusion
**00:00**

Intervention Period

Start rapid EEG as
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Observe without intervention

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Intervention Period

acquire for up to 4 hours

**00:15**
Data collection for response assessment

Study team arrives, takes over data collection and initiates efforts to notify and seek consent from LAR.

(If blood collection is being performed, study team collects 1st sample at 5-45 minutes)

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**01:00**
Primary outcome assessment

Anticipated onset of study drug action
Observe without intervention

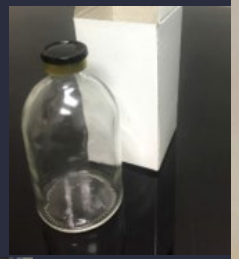
**00:15 – 01:00**
Rescue if
seizure occurs or continues

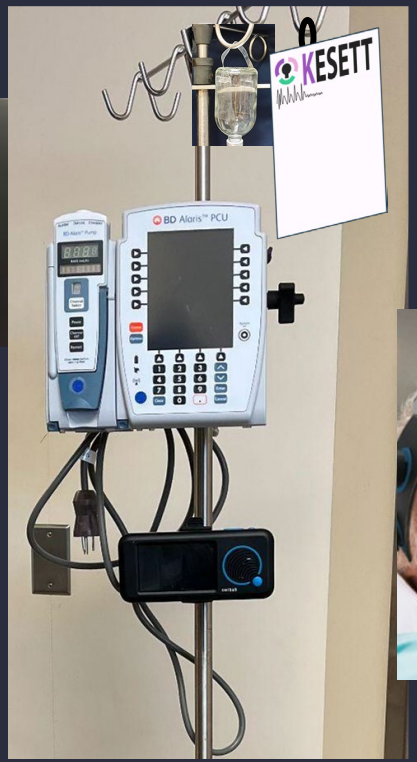
Standard Care

Complete enrollment CRFs in WebDCU
Replace study drug vial for next enrollment.
Recover rapid EEG after up to 4 hours.

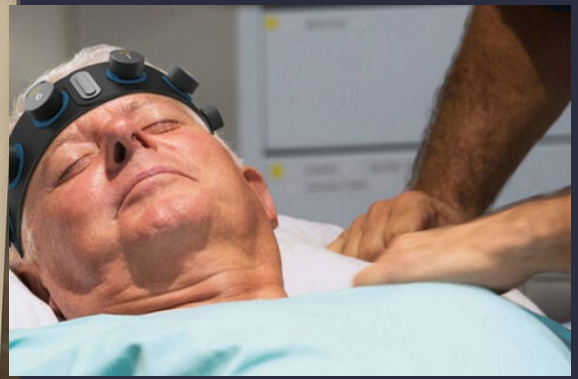
(If blood collection is being performed, study team collects 2nd sample at 60-120 minutes, and then process samples)

# Enrollment start









# WebDCU V2 Overview: Riley Luckmann DCC

# WebDCUv2 Access

- KESETT is housed in WebDCUv2 - this is a different website than WebDCUv1where all other previous and ongoing SIREN studies are housed.
- WebDCUv2 username and password are the same as WebDCUv1. If you change one, it does not automatically change the other.
- All PIs and PSCs have been granted regulatory access in KESETT to set up your DOA, upload regulatory documents, and submit EFIC forms. If additional members of your team will be assisting in this startup phase, email me (luckmann@musc.edu) with the team member's name, email, and site so that I can grant access.

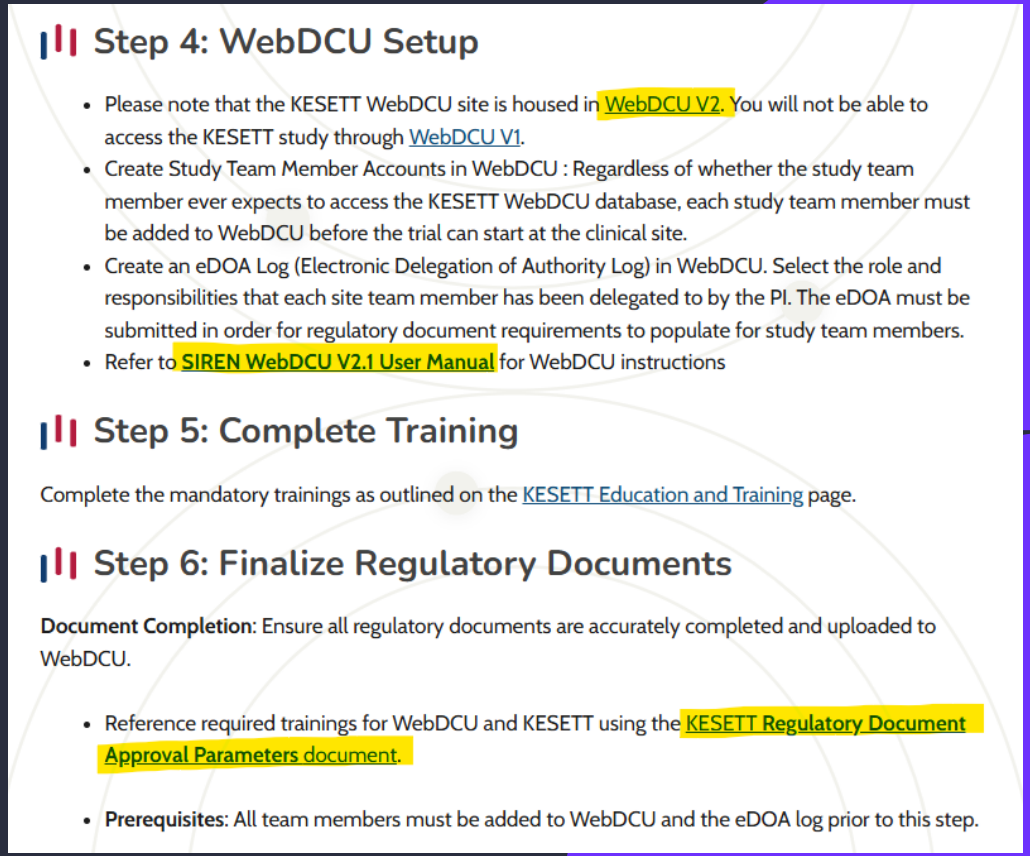
# WebDCUv2 Live Demo

- Setting up your study team
  - Request study team member
  - DOA Submission
- Uploading Reg Docs

# Resources

- WebDCUv2 link
- SIREN WebDCUv2 User Manual
- Regulatory Document Approval Parameters
- Riley Luckmann

  KESETT Data Manager
  luckmann@musc.edu



## Step 4: WebDCU Setup

- Please note that the KESETT WebDCU site is housed in WebDCU V2. You will not be able to access the KESETT study through WebDCU V1.
- Create Study Team Member Accounts in WebDCU : Regardless of whether the study team member ever expects to access the KESETT WebDCU database, each study team member must be added to WebDCU before the trial can start at the clinical site.
- Create an eDOA Log (Electronic Delegation of Authority Log) in WebDCU. Select the role and responsibilities that each site team member has been delegated to by the PI. The eDOA must be submitted in order for regulatory document requirements to populate for study team members.
- Refer to SIREN WebDCU V2.1 User Manual for WebDCU instructions

## Step 5: Complete Training

Complete the mandatory trainings as outlined on the KESETT Education and Training page.

## Step 6: Finalize Regulatory Documents

**Document Completion**: Ensure all regulatory documents are accurately completed and uploaded to WebDCU.

- Reference required trainings for WebDCU and KESETT using the KESETT Regulatory Document Approval Parameters document.
- **Prerequisites**: All team members must be added to WebDCU and the eDOA log prior to this step.

# Reporting EFIC Activity: Erin Bengelink CCC

# EFIC Activities

- **Same**
  - Regulations
  - Goals and mindset remain value-added, investigator engaged
  - Community Consultation
  - Public Disclosure
- **New**
  - Hybrid - Site/Centralized approach coordinated at University of Alabama (UAB)

- **What to do at your site**
  - **2 virtual focus groups moderated by UAB**
    - You will be asked to recruit about 8 stakeholders of differing perspectives for these groups. You can identify from where you may recruit these locally.
  - **2 in-person events**
    - Over the summer these may be fairs, festivals, markets, epilepsy strolls or other community events. Look at your community calendar and think about what you might do.
  - Review and share any new local institutional processes/policy
  - If you have an local event occurring in July that you would like to attend please contact the KESETT team
  - EFIC plan and CC/PD materials under IRB review and will be released as soon as they are approved

# EFIC Activities
# Things you can explore

**Focus groups** - Identify where to potentially recruit about 8 stakeholders of differing perspectives for each focus group session.

**Local Community Consultation** - Identify events, fairs, festivals, markets, epilepsy strolls or other community events. Look at your community calendar

**Public Disclosure** - Think about important neighbourhoods for focused disclosures

Review and share any new local institutional processes/policy

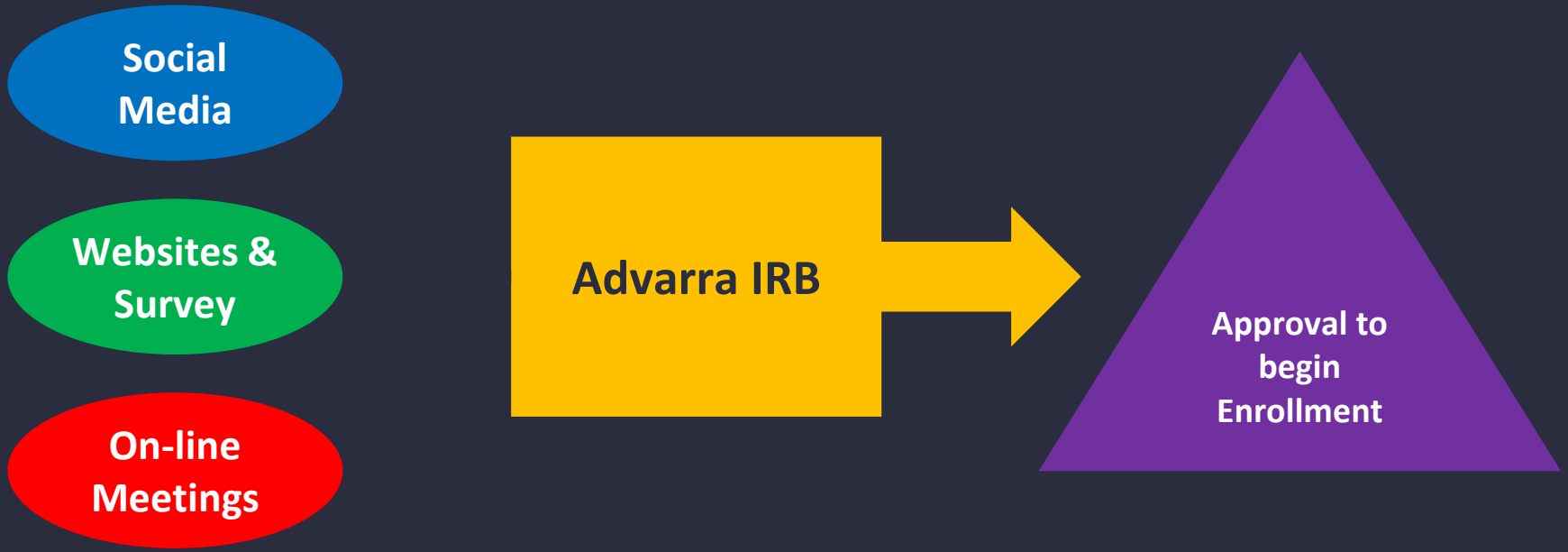
# How to Report EFIC activities to CCC

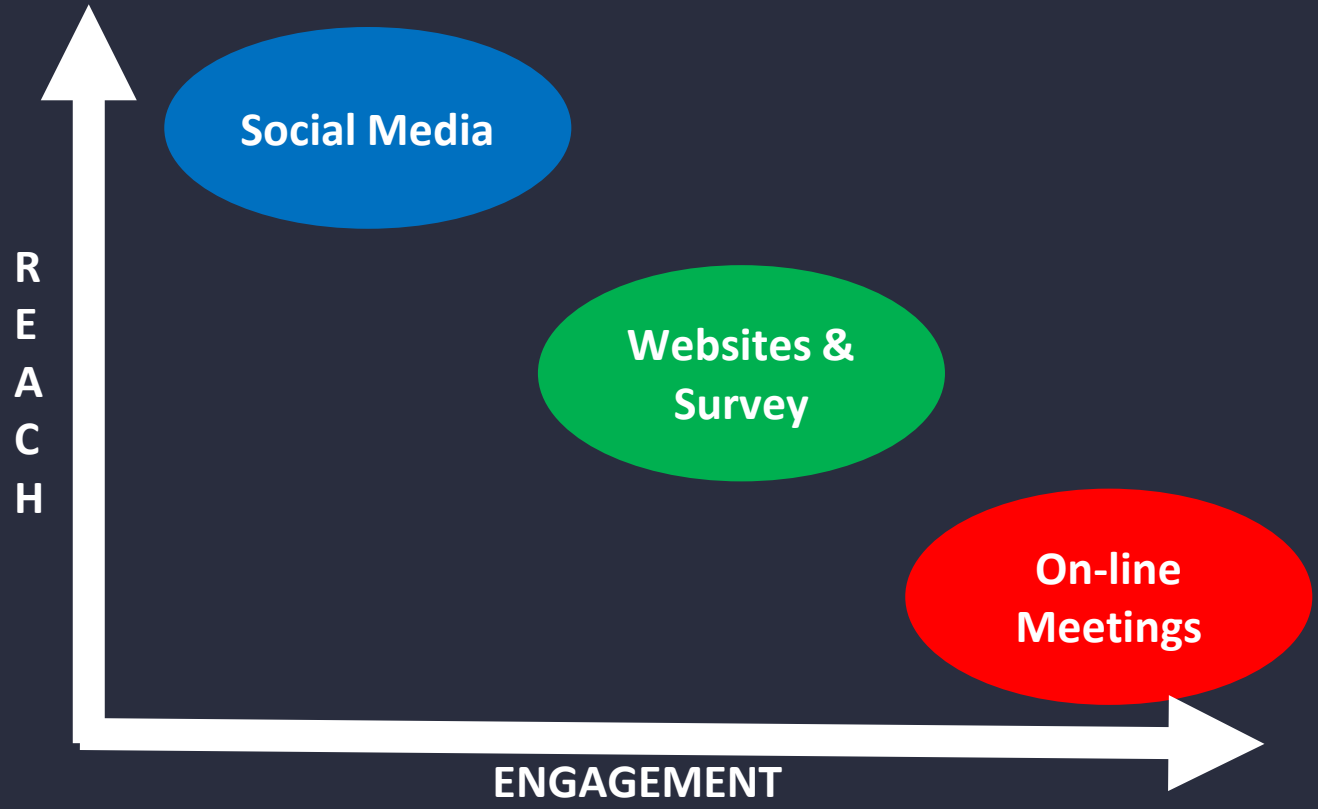
- Local Context Form
  - We request that your site completes this form as soon as possible
  - Provides key information for your local community
  - Key to coordinating centralized EFIC activities (specifically zip codes from local catchment area)
  - One form for each site should be completed in WebDCU
  - Reach out for guidance on how to complete If collaborating other sites
- CC Form
  - Complete one form for each activity

- PD Form
  - PD will take place centrally, however sites are welcome to do additional PD activities locally
  - Complete one form for each activity
- KESETT EFIC Forms Resource Guide
  - Provides additional instruction on completing EFIC forms
  - Can be found in the KESETT database under the EFIC tab, Additional EFIC Resources

# EFIC Core Overview: Shannon Stephens UAB

# Interactive, Media-Based Community Consultation and Public Disclosure for Exception-from-Informed-Consent




Social Media
Websites & Survey
On-line Meetings
REACH
ENGAGEMENT

JAMA Surgery | Original Investigation

# Interactive Media-Based Approach for an Exception From Informed Consent Trial Involving Patients With Trauma

Shannon W. Stephens, EMTP; Christy Carroll-Ledbetter, BA; Sarah Duckert, MBA; Tanner Coffman, MS; Margaret Nelson, BA; Karen N. Brown, MSHA; Joel Rodgers, MA; Russell L. Griffin, PhD; Amy Suen, PharmD; Jeremy Casey, MBA; Steven R. Sloan, MD, PhD; Brahm Goldstein, MD; Adam Joseph McClintock, MBA; Sara F. Goldkind, MD, MA; Luke Gelinas, PhD; Amanda E. Higley, PhD; Bellal A. Joseph, MD; John B. Holcomb, MD; Jan O. Jansen, MBBS, PhD; for the TAP Study Group

**IMPORTANCE** Exception From Informed Consent (EFIC) research requires community consultation (CC) and public disclosure (PD). Traditional methods of conducting CC and PD are slow, expensive, and labor intensive.

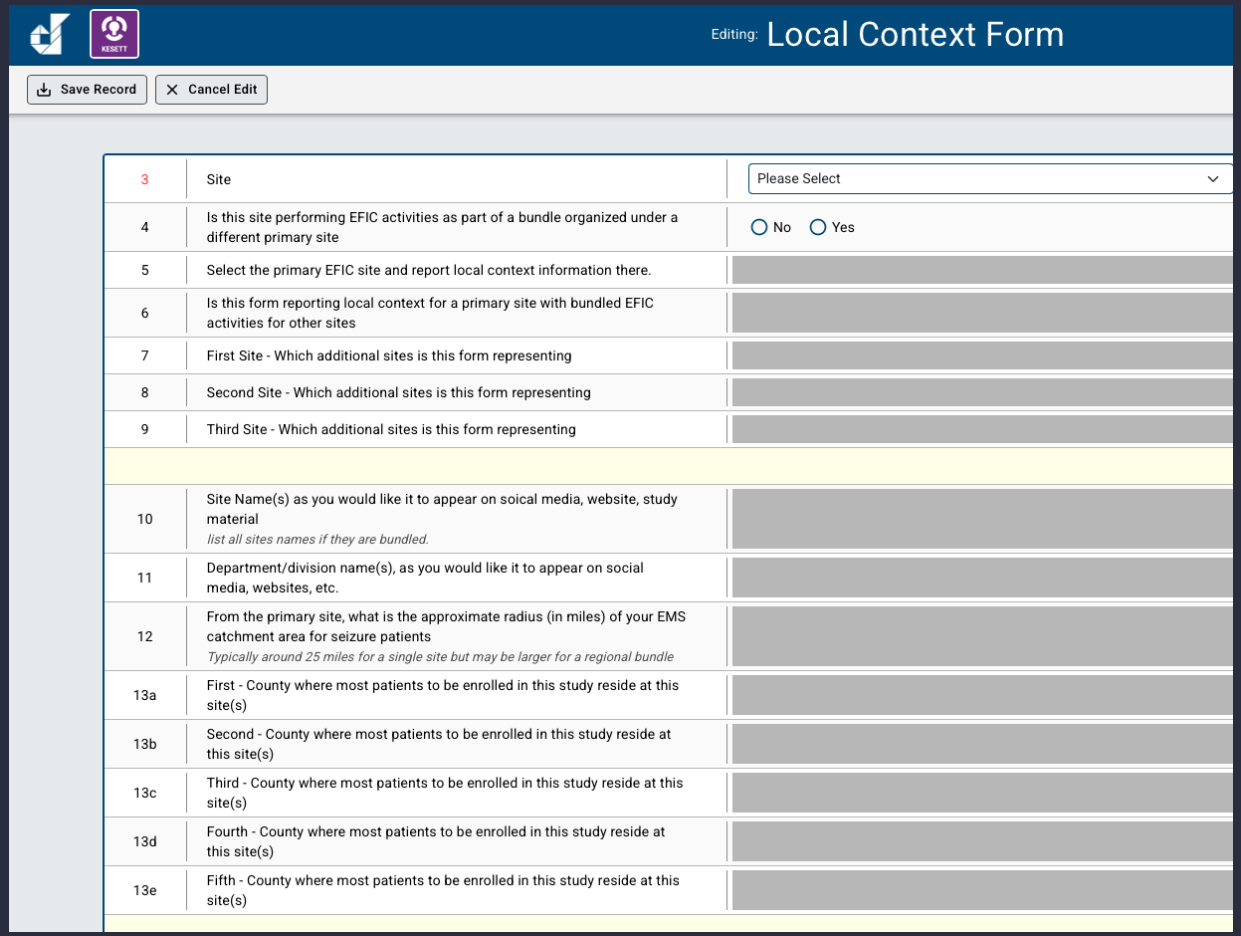
**OBJECTIVE** To describe the feasibility and reach of a novel interactive, media-based approach to CC and PD and to identify the similarities and differences between trial sites in website views, survey responses, online community forum attendance, and opt-out requests.

**DESIGN, SETTING, AND PARTICIPANTS** This survey study analyzed the CC and PD campaigns conducted for the TAP trial (Evaluation of BE1116 in Patients With Traumatic Injury and Acute Major Bleeding to Improve Survival), an EFIC trial of the early administration of prothrombin complex concentrate in patients with trauma. The CC and PD campaigns consisted of social media advertisements, linked websites, community surveys, and online community forums. These activities were coordinated from a central site and approved by a central institutional review board. This study focused on the first 52 of 91 TAP trial sites (level I trauma centers) in the US to have completed their CC and PD campaigns. Community members in the catchment areas of the participating trauma centers were targeted. Data analysis was

Invited Commentary
page 1058

Supplemental content

# Information Needed



# Social Media Campaign

Method: Facebook/Instagram advertisement, with linked website

Purpose: Provide information, receive comments

Geographic Specific

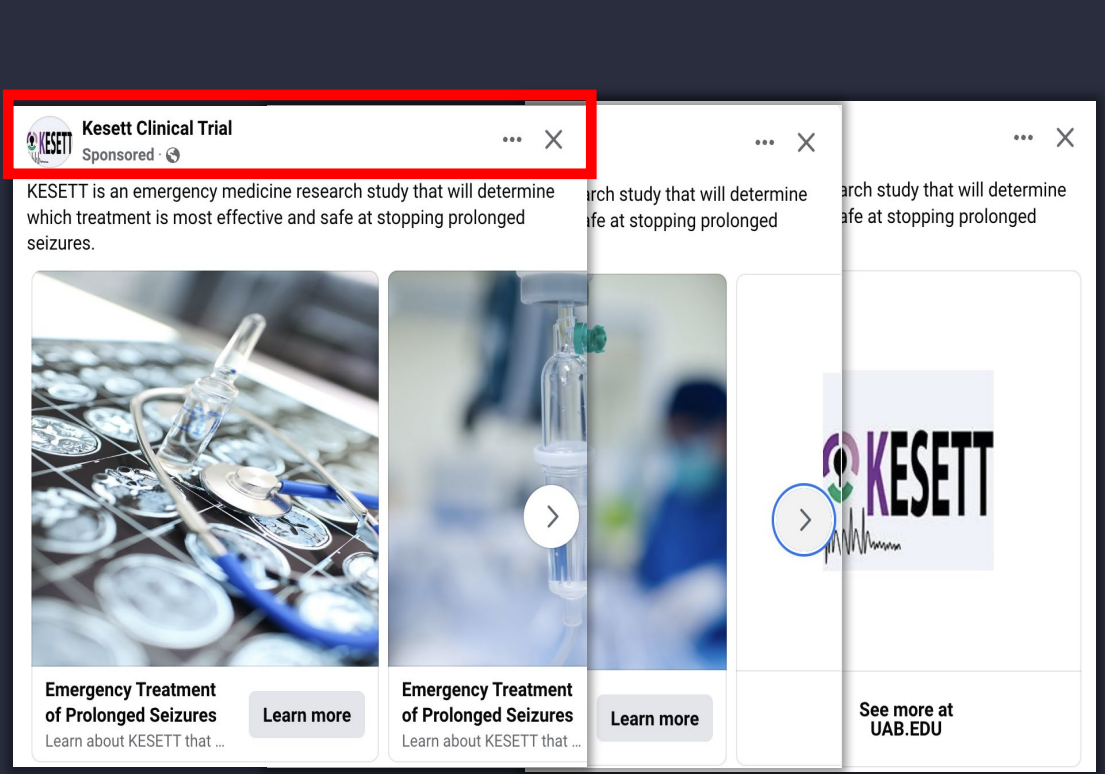
Target Demographic Group

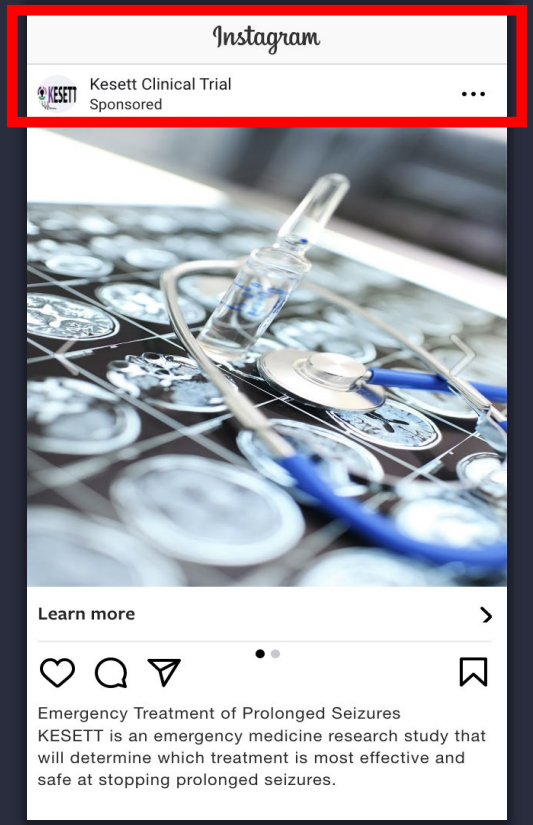
Target At-Risk populations

**Provide information**

**Receive feedback**

# Ad 1: Geo-Targeted Zone

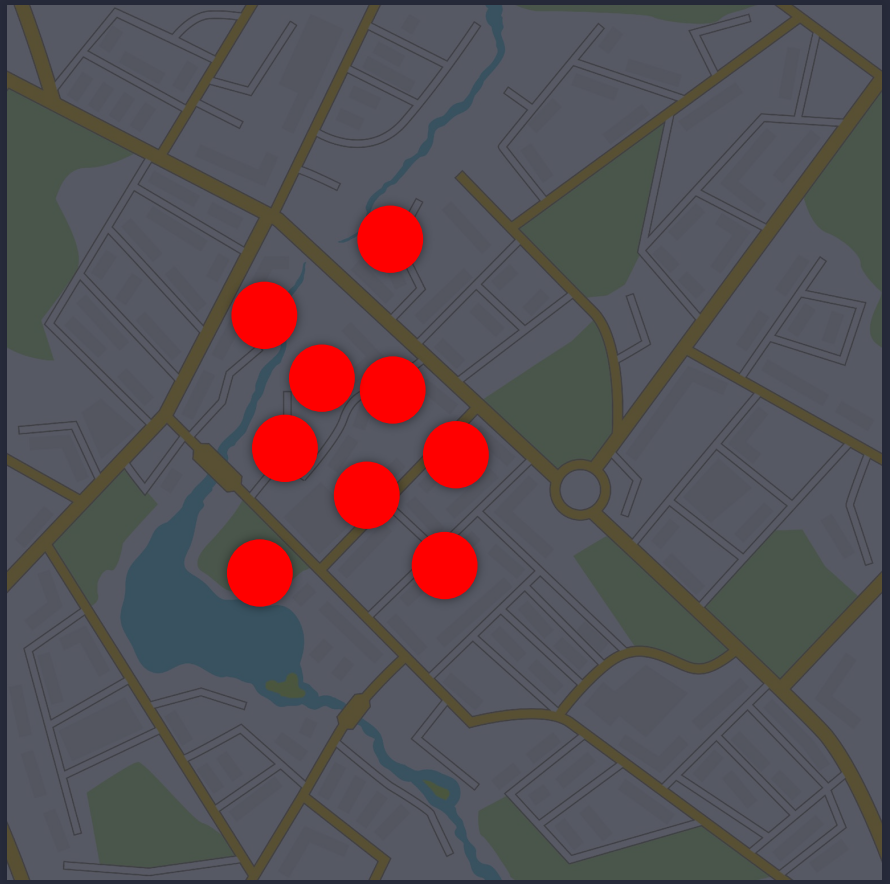


# Ad 1: Geo-Targeted Zone

# Ad 2: Zip Codes





facebook.com

KESETT all Site call - Google Slides | UAB-Home – KESETT Trial | WebDCU™ for SIREN Current User: Shannon STEPHENS | Facebook

Search Facebook

Shannon Stephens
Meta AI
Friends
Memories
Saved
Groups
Video
Marketplace
See more

Your shortcuts

Lake Logan Martin Residents Only
Whats Really Happening In Pell City
See more

Privacy · Consumer Health Privacy · Terms · Advertising · Ad Choices · Cookies · More · Meta

$140 · COLUMBUS, OH
Nike Vapor Fly Driver - Left Handed
Message

1 comment

Like Comment

Kesett Clinical Trial
Sponsored ·

KESETT is an emergency medicine research study that will determine which treatment is most effective and safe at stopping prolonged seizures.

Emergency Treatment of Prolonged Seizures
Learn about KESETT that ...
Learn more

Emergency Treatment of Prolonged Seizures
Learn about KESETT that ...
Learn more


See more at UAB.EDU

Like Comment Send Share

Titleist
Sponsored ·

"I've never hit a ball that high in my life." Watch as Michael Greller gets fit for T-Series Irons by Jordan Spieth and JJ Van Wezenbeeck.

Birthdays

Mike Adams and Lauren Phillips Holland have birthdays today.

Contacts

Meta AI
Kim White Gregory
Kristi King Randall
Danielle Bolton Bryant
Wendee Dulaney
Eva Winfrey
Beverly Edwards
Anna Bolton Webb
Jennifer Yates
Shawn Austin
Ric Carrizales
Linda Brindley Thompson
Derrick Wright
Gerald Cates

KESETT TRIAL AT UAB

# Ketamine in Established Status Epilepticus Treatment Trial (KESETT)

Click to complete the UAB Medical Center EFIC KESETT Trial survey

## Ketamine in Established Status Epilepticus Treatment Trial (KESETT)

Seizures are a medical emergency that can occur in children and adults. Most seizures are short and stop on their own. These are scary, but are not usually dangerous. Prolonged seizures that do not stop on their own, however, are

# Ensayo pediátrico de reanimación prehospitalaria de las vías respiratorias

PEDI-PART
Pediatric Prehospital Airway Resuscitation Trial

Para ver el vídeo de Pedi-Part, haga clic aquí.

Cuando un niño sufre una enfermedad o un accidente que pone en peligro su vida, los Servicios Médicos de Emergencia (SME) suelen ser los primeros en llegar al lugar y los primeros en realizar estrategias médicas que salvan vidas para restablecer o mantener la respiración antes de que el niño pueda llegar al hospital.

El estudio Pedi-PART está diseñado para determinar la mejor estrategia para restablecer o mantener la respiración en los niños.

Actualmente, existen tres métodos que el personal de los SME utiliza para mantener o restablecer la respiración en los niños:

1. Ventilación con mascarilla con bolsa y válvula (BVM, por sus siglas en inglés): los paramédicos colocan una máscara ajustada en la parte superior de la cara e introducen oxígeno por la boca y la nariz hasta los pulmones.
2. intubación endotraqueal (IET): los paramédicos colocan un tubo de plástico en la garganta a través de la laringe e introducen oxígeno en la tráquea y los pulmones.
3. inserción de vía respiratoria supraglótica (SGA, por sus siglas en inglés): los paramédicos colocan un tubo especial por la boca hasta la garganta, por encima de la laringe, e introducen oxígeno en la tráquea y los pulmones.

En este estudio, determinaremos qué método funciona mejor para la supervivencia infantil comparando los 3 métodos que los profesionales de emergencias médicas utilizan a diario para manejar las vías respiratorias y apoyar la respiración.

A las agencias de SME participantes se les asignará el uso de un método diferente cada día, esto les permitirá a los investigadores comparar la eficacia de cada método. Si el método asignado no tiene éxito, los SME podrán socorrer con cualquier otro método para las vías respiratorias.

En el ensayo participarán agencias de SME de 10 ciudades de todo Estados Unidos, las cuales colaboran con la Red de Investigación Aplicada a la Atención de Emergencias Pediátricas (enlace a PECARN).

# Surveys

Method: Qualtrics survey software (not linked to social media)

Purpose: Receive comments

## Online survey using Qualtrics

Surveys targeted to individuals who reside in counties within the catchment area of each participating center.

The KESETT study is being performed so that doctors can know the best medications to use in the emergency department to treat people with prolonged seizures. KESETT will compare the anti-seizure medication most commonly used in those with prolonged seizures, called levetiracetam (also known as Keppra), compared with a combination of levetiracetam and another anti-seizure medication, called ketamine.

This study is being done before we can obtain subject consent due to the nature of the emergency. Consent will be sought as soon as possible after treatment.

**https://sites.uab.edu/kesett/uab-home** , click here

Do you have any comments you would like to tell the researchers about this study? We would value your feedback via the link below. Your feedback will remain confidential

→

- 7-question survey regarding respondents willingness to be enrolled in KESETT Trial, family members enrolled, belief about emergency research, and belief in this trial should be done in their community.

- Additional 10 questions regarding demographic information about the survey respondent. (age, sex, race, health literacy, education level, how many people in your home, household income, zip code)

- Additional comments box regarding KESETT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N=2,945+50
2995


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Jefferson, AL
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Shelby, AL
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St. Clair, AL
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Tuscaloosa, AL
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Walker, AL
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Gila, AZ
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La Paz, AZ
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Pima, AZ
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Santa Cruz, Az
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Essex, MA
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King, WA
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Kitsap, WA
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Mason, WA
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Pierce, WA
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# Focus Group Community Meetings

Method: Site to identify 2-groups of at-risk individuals

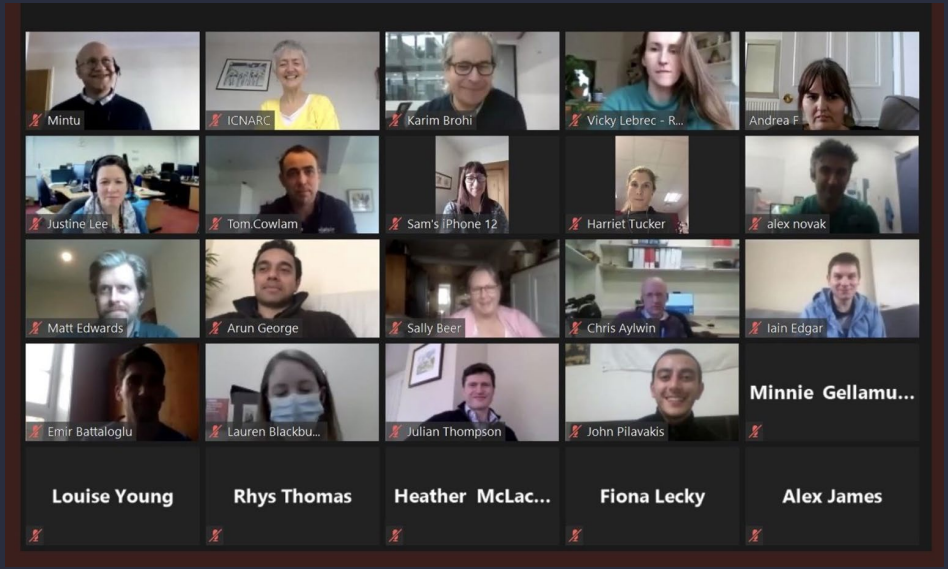
Purpose: Provide information, receive comments

Geographic Specific

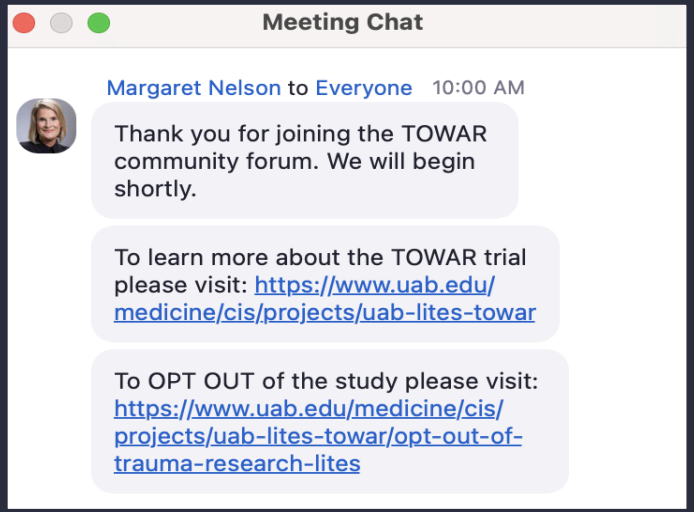
Target Demographic Group

Target At-Risk populations

# Focus Group Meetings targeted to at-risk groups within the community




**Provide information**
**Receive comments**
**Learning from the local community**



TAP
TRAUMA AND PCC STUDY

1

## GOALS TODAY

1. Study Overview
2. Enrollment process
3. Questions or Concerns

2

Clinical research is important

3

4

TAP
TRAUMA AND PCC STUDY

5

Does Prothrombin Complex Concentrate increase survival?

6


7

All other treatments are the same

8

Are there risks?

9

Patients with life-threatening injuries and serious bleeding

10

Informed Consent

11

12

Exception from Informed Consent (EFIC) Research

13

Food and Drug Administration (FDA)

Institutional Review Board(s) (IRB)

14

Community Consultation & Public Disclosure

15

Patients and guardians / relatives will be informed at the earliest opportunity

16

CSL Behring


17

Community Feedback

18

- Do you believe that emergency medical research is necessary?
- Do you believe that this study should be done in your community?
- If you were severely injured and needed blood transfusions, would you want to be enteres into this research study, even though you couldn't give consent?

19

- If one of your family members was severely injured and needed blood transfusions, would you want them to be entered into this research study, even if they or you couldn't give consent?
- If no to either of these two questions, what do you believe would be the reason for concern?
- Do you have any other questions you would like to ask the local lead physician regarding the study?

20

Thank you for participating

TAP
TRAUMA AND PCC STUDY

21

# Reporting on the engagement

Social Media

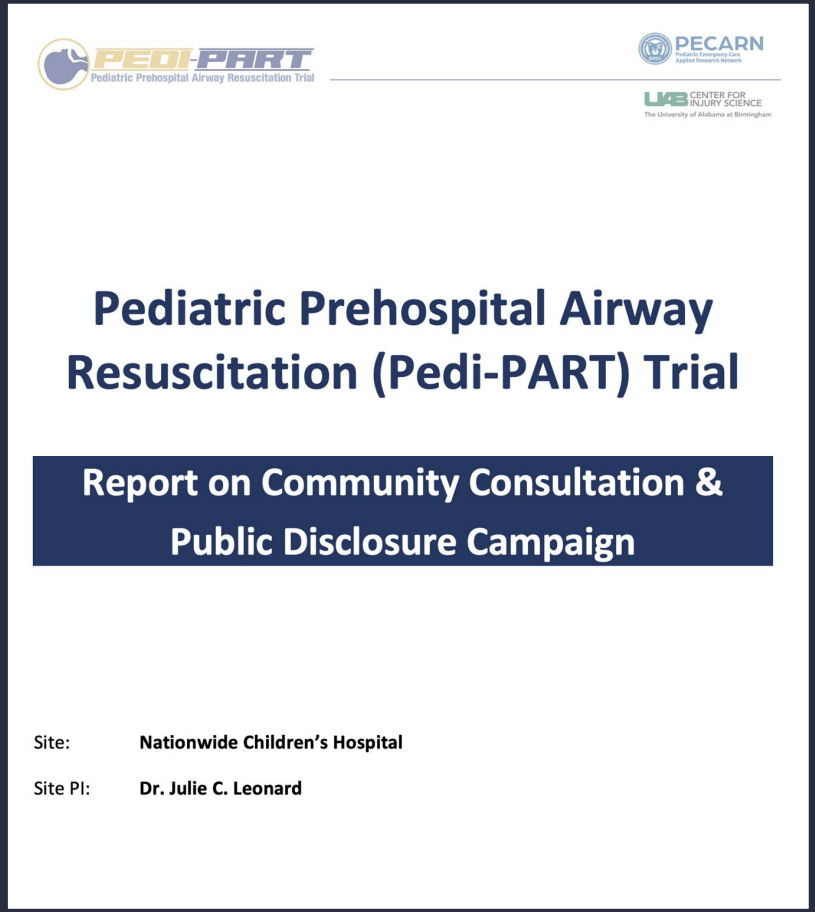
Survey

Online Meetings


2 months to complete

# Site Summary Report for IRB Submission

- ~ 50 pages
- Executive Summary
- Site Demographics
- SM Results
- Web page visits
- Survey results
- Focus Group summaries
- Opt out request



# Local PI Responsibilities

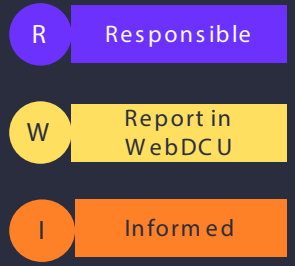

Initial institutional approval


Flyers


Leading focus Group meetings

# EFIC Task Responsibility

| | CCC | Site Team | EFIC Core |
|---|---|---|---|
| Local IRB Ceding | I | R | |
| WebDCU Local Context form | I | R W | |
| EFIC Community Events | I | R W | |
| EFIC Focus Groups | I | R | R W |
| EFIC Online Public Disclosure | I | | R W |
| EFIC Report | I | | R |
| Site CIRB Submissions | R | I | |

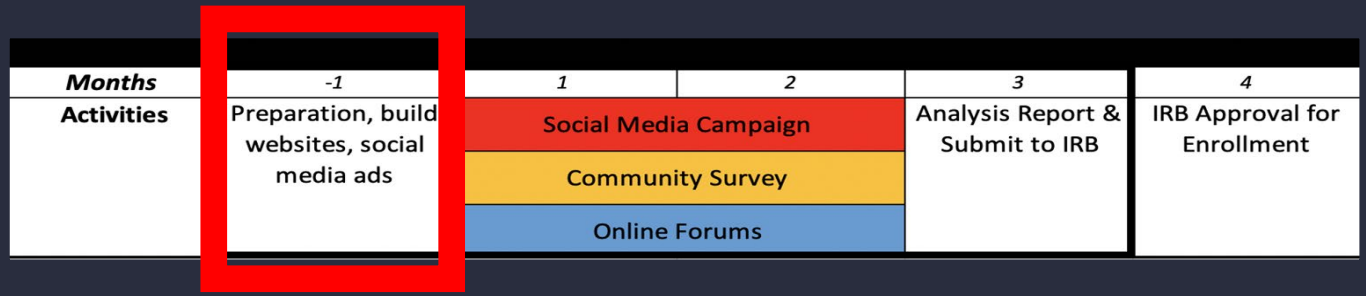


# Steps & Timeline

| *Months* | *-1* | *1* | *2* | *3* | *4* |
|---|---|---|---|---|---|
| **Activities** | Preparation, build websites, social media ads | Social Media Campaign | | Analysis Report & Submit to IRB | IRB Approval for Enrollment |
| | | Community Survey | | | |
| | | Online Forums | | | |

1. Verify the data in WebDCU is reasonable and complete.
2. Pre-build the Facebook ads using Radius, ZIP Codes, and At-risk community groups.
3. Finalize the site-specific websites and ensure google tracking code is imbedded on each.
4. Coordinate a conference call with the site to review the Facebook ads, survey, and webpages.
5. Allow site to seek local IRB input if required.
6. When site approved (if needed by local IRB) launch CC/PD campaign.

# Steps & Timeline



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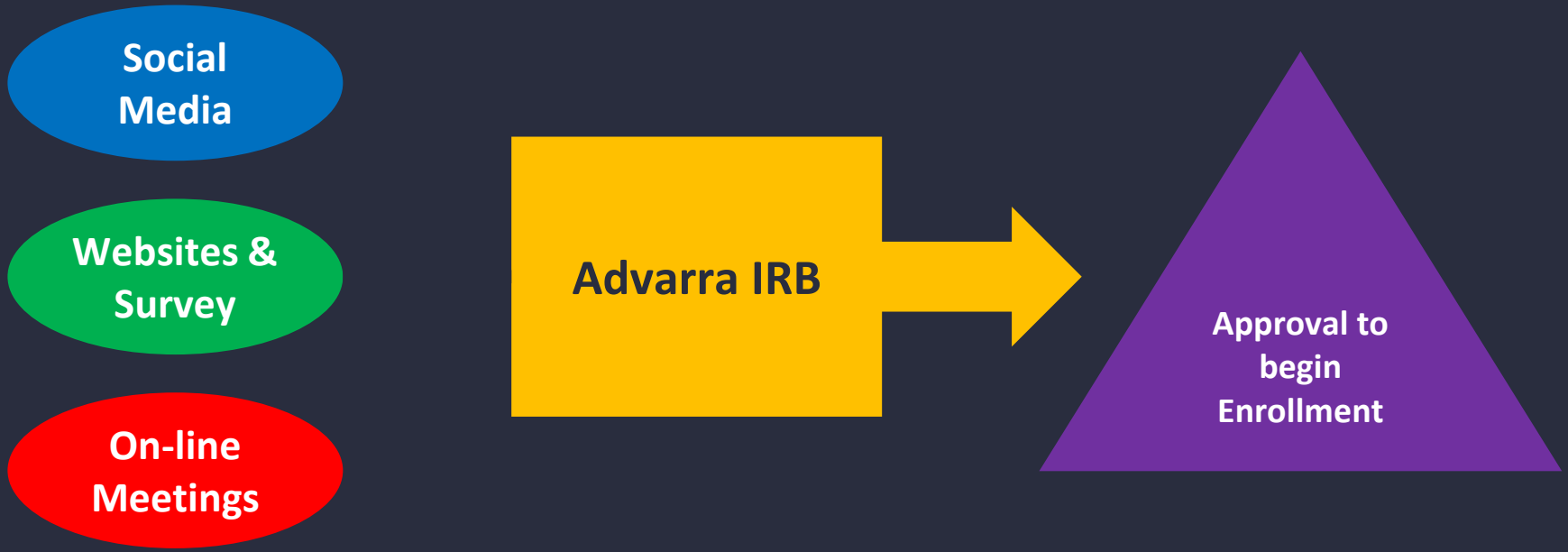
# Questions?


Social Media
Websites & Survey
On-line Meetings
Advarra IRB
Approval to begin Enrollment

# Ceribell & Study Drug: Megan Wardius UVA

# Ceribell Overview

- Ceribell is a POC EEG system that will be used for rapid EEG.
  - EEG headband: single use available in 2 sizes
  - EEG recorder
  - Cloud portal: KESETT has a dedicated research portal
- rEEG: started as close to the start of study drug as possible and continue for up to 4 hours.
- Recorders & headbands will be provided by the study; there will be a monthly inventory process for headbands.
- Ceribell equipment should be stored close to/in the enrollment area and accessible to clinical & research staff.
- No patient identifiers should be entered into the EEG recorder- the study drug ID will connect the EEG to the participant.

# Ceribell cont.

- Ceribell site start up activities:
  - Refer to Ceribell Implementation Guide (Found under Workbench)
  - Local IT approval process
  - Connect to Wifi network
  - On-site training with Ceribell representative
  - Sites do not need a direct agreement with Ceribell; terms are included in trial agreements.

- **Sites that use rapid EEG in their ED routinely for clinical purposes will have different workflow. Reach out to Vince if this applies to your site to discuss.**

# Study Drug Overview

- KESETT study drugs are formulated by the UC Davis GMP facility.
  - 3rd party testing for sterility, concentration, stability, & more is done by ARL BioPharma.
- All 3 formulations are identical in appearance and packaging.
- 2 vial fill volumes in same size bottle:
  - 35mL: For participants <30kg.Purple label
  - 90mL: For participants ≥30kg. White label
- Vials are provided to sites in a cardboard box to protect from light.
- Study drug dose is based on weight-based dosing.
  - Dose administration chart is included in the box & on protocol reminder cards.

# Study Drug cont.

**Table 3. Dose Administration Chart**

| Estimated Participant Weight (kg) | Infusion Vol. (mL) | Infusion Rate (mL/min) over 5 min | LEV (total dose in mg) | KET 1mg/kg (total dose in mg) | KET 3mg/kg (total dose in mg) |
|---|---|---|---|---|---|
| 10 to <12.5 | 11 | 2.2 | 660 | 11 | 33 |
| 12.5 to <15 | 13 | 2.6 | 780 | 13 | 39 |
| 15 to <20 | 17 | 3.4 | 1020 | 17 | 51 |
| 20 to <25 | 22 | 4.4 | 1320 | 22 | 66 |
| 25 to <30 | 27 | 5.4 | 1620 | 27 | 81 |
| 30 to <35 | 32 | 6.4 | 1920 | 32 | 96 |
| 35 to <40 | 37 | 7.4 | 2220 | 37 | 111 |
| 40 to <50 | 45 | 9.0 | 2700 | 45 | 135 |
| 50 to <60 | 55 | 11 | 3300 | 55 | 165 |
| 60 to <70 | 65 | 13 | 3900 | 65 | 195 |
| ≥70 | 75 | 15 | 4500 | 75 | 225 |

# Study Drug cont.

- Study drug is stored at room temperature (20 -25*C ± 2*C).
- Study drug should be stored in a secure location that is easily accessible from the enrollment area for both clinical & study teams.
    - Expect this to be drug dispensing system for most sites.
- A single vial for each weight strata will be stored in the ED to be used for the next enrollment.
    - Enrollment CRF in WebDCU triggers drug resupply to the site with treatment allocation.
    - Backup vials will be provided to be stored in the site's Investigational Pharmacy.
    - After enrollment, backup vial is placed in the ED in case another enrollment occurs before next assigned vial arrives. Once the new vial has arrived, this should replace the back up vial.

# Any questions? Ask away!