



# NETT-Workings

## NEUROLOGICAL EMERGENCIES TREATMENT TRIALS (NETT) NETWORK

JANUARY 2016

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### PARTICIPATING HUBS AND INVESTIGATORS

#### National Institute of Neurological Disorders and Stroke (NINDS)

Clinical Trial Group  
 Robin Conwit, MD and Scott Janis, PhD

#### CLINICAL COORDINATING CENTER (CCC)

University of Michigan  
 William Barsan, MD

#### STATISTICAL & DATA MANAGEMENT CENTER (SDMC)

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Enrollment Update: As of 1-28-16 at 1:35p (EST)

**ESETT**

**POINT**

**SHINE**

<b>Arizona</b>	<5	<b>52</b>	<b>8</b>
<b>Cincinnati</b>	<5	<b>151</b>	<b>19</b>
<b>Emory</b>	<b>5</b>	<b>83</b>	<b>86</b>
<b>HFH</b>	<5	<b>52</b>	<b>5</b>
<b>Kentucky</b>	<5	<b>51</b>	<b>39</b>
<b>Maryland</b>	<5	<b>43</b>	<b>9</b>
<b>Mass General</b>	<5	<b>47</b>	<b>12</b>
<b>Minnesota</b>	<5	<b>138</b>	<b>11</b>
<b>NYP</b>	<5	<b>57</b>	<b>90</b>
<b>Ohio State</b>	<5	<b>20 (Emmes/NETT)</b>	<b>57</b>
<b>OHSU</b>	<5	<b>58</b>	<b>6</b>
<b>Pittsburgh</b>	<5	<b>22</b>	<b>36</b>
<b>SUNY Downstate</b>	<5	<b>92 (Emmes/NETT)</b>	<b>15</b>
<b>Stanford</b>	<b>5</b>	<b>115</b>	<b>27</b>
<b>Temple</b>	<5	<b>74</b>	<b>28</b>
<b>Texas</b>	<5	<b>98</b>	<b>36</b>
<b>UCLA</b>	<5	<b>34 (Emmes/NETT)</b>	<b>10</b>
<b>UCSF</b>	<5	<b>71</b>	<b>11</b>
<b>UPenn</b>	<5	<b>260</b>	<b>26</b>
<b>VCU</b>	<5	<b>12</b>	<b>&lt;5</b>
<b>Wayne State</b>	<5	<b>145</b>	<b>16</b>
<b>Wisconsin</b>	<5	<b>77</b>	<b>12</b>
<b>PECARN Sites (ESETT only)</b>	<5	-	-
<b>Emmes + Harrison (POINT only)</b>	-	<b>1715</b>	-
<b>Ancillary Sites (SHINE only)</b>	-	-	<b>184</b>
<b>TOTAL</b>	<b>25</b>	<b>3387</b>	<b>743</b>

## PLEASED TO MEET YOU NETT...

### **Robin Conwit, MD** **NIH/NINDS Program Director for the NETT**



Dr. Robin Conwit is a program director in the NINDS Clinical trials cluster with a background in neuromuscular disease and clinical neurophysiology. Most recently she was a neurology department faculty member at Johns Hopkins subspecializing in electromyography and neuromuscular disease, with clinical trials experience in ALS and diabetic neuropathy. Her prior experience also includes running an ALS Clinic at the University of Pittsburgh where she was the principal investigator for ALS clinical trials. Dr. Conwit earned a bachelor's degree from Colgate University, where she was a Phi Beta Kappa graduate, magna cum laude; attended medical school at the University of Buffalo; and completed a residency in Neurology at George Washington

University, followed by a fellowship in electromyography at NIH. Her current interests include Neurological Emergencies Treatment Trials, neurologic intervention studies, and adult neuromuscular diseases including ALS and neuropathies.

Dr. Conwit has another full time job as the mother of two sons in college. In her spare time Dr. Conwit enjoys hiking with her Vizsla, skiing, exotic travel, attending the theater and concerts both classical and contemporary, and drinking espresso.

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### **Scott Janis, PhD** **NIH/NINDS Program Director for the NETT**

Dr. Scott Janis has been with NINDS since 2001 and is currently a Program Director in the Office for Clinical Research. His main areas of scientific interest include clinical trials in stroke. He oversees two clinical trials' networks at NINDS, including the NINDS Stroke Trials Network and the NETT. Prior to joining NINDS, Dr. Janis received his training in Neuroscience from the School of Medicine at the Georgetown University Medical Center and the Center of Molecular and Behavioral Neuroscience at Rutgers University.



The picture to the right is of Dr. Janis' son playing baseball, who just turned 12 years old last month. Dr. Janis states that his son "looks enough like me", and is almost as tall too at 5'6". Baseball is a pretty big hobby in the Janis household. When Dr. Janis is not playing doctor for the government he is coaching baseball. He comments that he actually thinks that is probably his full time (unpaid) job and the rest of his time is working at NIH. Two all time favorite family activities include visiting Disney and Colonial Williamsburg.



Principal Investigator: **Andnan Qureshi, MD**

A+

## PERFECT Form 5: Study Drug Infusion and 24 Hour Monitoring

To complete **Form 5: Study Drug Infusion and 24 Hour Monitoring** over 200 data points need to be entered from multiple source documents. There were five Form 5s completed perfectly. The NETT provided \$10 Target gift cards for perfect Form 5s. Congratulations to the following study coordinators:

★ **Melissa Freese**, St. Cloud Hospital (2 perfect forms)

★ **Vernon Kalugdan**, Temple University

★ **Anita Visweswaran**, Santa Clara Valley Medical Center

★ **Mike Lunney**, Emory University Hospital

-**Donna Harsh** ([dkharsh@umich.edu](mailto:dkharsh@umich.edu))



## Platelet-Oriented Inhibition in New TIA Trial

Principal Investigator: **Clay Johnston, MD**

### Lost to Follow-up Subjects

Currently, about 4% of subjects are considered to be lost to follow-up. To help minimize this rate, it is critical to document attempted contacts in the subject's *Form 17-End of Study* in WebDCU, using the guidelines set out in the study [protocol](#) (section 9.4.2.1). This information will be useful in providing feedback on the effectiveness of those guidelines. These include:

- At least three attempts to reach the subject by telephone
- At least one letter sent via Certified Mail™, with Return Receipt Service requested (or equivalent in other countries) for evidence of delivery to the participant's address, allowing one week for the subject to respond

If the subject consented to allow alternative contacts to provide information for follow-up, please document attempts to reach those alternates in the subject's record as well.

Even when subjects cannot be contacted despite the site team implementing the approaches above, investigators should, at minimum, determine each subject's health status at 90 days (e.g., living or deceased).

-**Renee Kasperek-Wynn** ([kasperr@umich.edu](mailto:kasperr@umich.edu))



## Clinical Trials Methodology Course

Principal Investigator: **William Meurer, MD, MS**

We are pleased to announce that the NINDS Clinical Trials Methodology Course (CTMC) is now accepting applications for the 2016 cohort. The CTMC is an intensive, engaging program designed to help junior investigators develop scientifically rigorous, yet practical clinical trial protocols. The CTMC features a combination of distance learning activities and a residential course, along with small group mentorship from experienced clinical trialists and biostatisticians. The residential course will be held on August 7-11, 2016 in Ann Arbor, Michigan. Funding for travel and accommodations will be provided. Application forms and additional details are available on the course website <http://neurotrials.training>.

If you have any questions please contact [NINDS-CTMC-Info@umich.edu](mailto:NINDS-CTMC-Info@umich.edu) or the CTMC Principal Investigator, William Meurer, MD, MS [wmeurer@umich.edu](mailto:wmeurer@umich.edu).

-**Samkeliso Beusterian** ([smawocha@umich.edu](mailto:smawocha@umich.edu))



## Protocol Assist Device and Instructions for Inclusion

### Device Set-Up



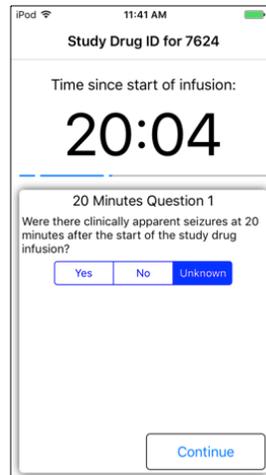
When loading Use Next box, scan barcodes in WebDCU and on drug vial to confirm study drug ID and allow for unblinding.

### Timing of Study Drug Infusion



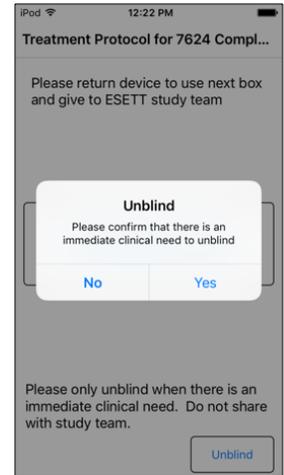
Select 'Start Protocol' when study drug infusion starts. Device will alarm at 10 min with a reminder to stop study drug infusion.

### 20/60 Min Assessments



Device will alarm at 20 & 60 min and prompt for responses about clinical apparent seizures and improved responsiveness.

### Routine Unblinding



After completion of the 60 min assessment, there is an option to unblind when there is an immediate clinical need.

#### Other Device Reminders:

- Regularly charge iPods & confirm network connectivity (so that alerts to study team members will trigger when the app is activated)
- Teach clinical team how to power on (Press and hold Sleep/Wake button for ~10sec). NOTE: See pocket card in Use Next box.
- Always fully charge and power down after use, and ensure that volume is turned up all the way so that prompts can be heard.



## User Permissions and the eDOA (ESETT and SHINE)

### Adding a Team Member to ESETT and SHINE

Adding a team member and requesting his/her user permissions are *2 separate steps*, and must be completed for each study individually. Follow these instructions for each study:

1. From the study's main menu page, click on [User Management], then [Study Team Member Request]. Click "Add New", and fill out the team member's information. If your team member already has a WebDCU account, please be sure to select "Select from existing WebDCU member." Then, click "Save Record." In the List Record view, if the column "Request Process Status" reads "Approved," then the request was successful.
2. To request permissions for the user you added, click on the [User Permission Request] tab. On the list record page, click on the blue link in the # column to the left of the study team member name you are looking for.
3. Click on "Edit Record" on the top right corner of the page. Add drop down boxes in question 8 with each of the user permissions this team member should have. Click "Add New Row" to add more user groups. Always be sure to give all team members access to the "WebDCU User" user group. Finally, click [Save Record].
4. Please note that all user permission requests will remain in pending status until the team member is added to the eDOA and it is approved. Once the eDOA is approved, the data manager will verify and approve the request.

### Removing a Team Member in ESETT and SHINE

Follow the instructions below for each study:

1. Click on [User Management] tab, and then [User Permission Request].
2. On the list record page, click on the blue link in the # column to the left of the team member you are looking for.
3. Click on "Edit Record" in the top right corner of the page. Remove all user group permissions by selecting the blank option in each drop down box in question 8. When done, click "Save Record." Please be sure to add an end date for this user on the eDOA Log under section 5: Active Team Member.
4. The data manager will then review and approve this request, removing the permissions.

-Kavita Patel ([pateka@umsc.edu](mailto:pateka@umsc.edu))