

Validation of Early Prognostic Data for Recovery Outcome after Stroke for Future, Higher Yield Trials

Newsletter September 2022 Issue 9

# **Enrollment Updates**



"Special thanks to
Emory and UT-Houston
for giving us a kickstart
by enrolling 3 patients
each in just the first
month of activation!!
And thanks to all of our
sites for pushing the
study forward. It is really
great to see our
recovery stroke
community in action!"

-Pooja Khatri, MD, MSc

**Medstar Washington Hospital:** 1 participant

**Emory University:** 3 participant

**UT Memorial Hermann:** 3 participants

## Sites Released to Enroll

- University of Cincinnati
- Emory University
- Medstar Washington Hospital Center
- UT Memorial Hermann
- University of Michigan
- Medical University of South Carolina
- University of Utah
- Duke University

### **Payment Schedule**

- Rather than sending separate payments to compensate the healthy volunteers, we have instead included these funds in the site startup payment. Thus, the site startup payment has been increased from \$8250 to \$9250.
- This continues to allow for compensation of a healthy volunteer at \$25 per TMS training session for up to 4 sessions per volunteer (maximum \$100), and up to 40 training sessions per site (\$1000) towards healthy volunteer training.
- However, it will eliminate some added invoicing and tracking effort for our coordinators. Furthermore, if funds
  are not fully utilized for Healthy Volunteer training, they may be rebudgeted for other VERIFY start-up expenses.

#### Webinars

- PI webinars occur on the 3rd Monday of each month, 4pm-5pm ET.
- CRC webinars occur on the 4th Tuesday of each month, 12pm-1pm ET.
- Weekly drop-in TMS help sessions are also available as detailed below.

\*Zoom meeting series have been sent to all sites for the PI webinars, CRC webinars & drop-in TMS sessions\*

## **TMS Reminders**

- We recommend that TMS operators complete 1 healthy volunteer TMS session & wait for feedback before proceeding with the next healthy volunteer TMS session. This way, TMS operators can incorporate feedback and make corrections before performing their next healthy volunteer TMS session.
- We also recommend re-reading the "7. TMS Source Document" and "8. Practical TMS Training with Healthy Volunteers" pages on the TMS training website before starting practical training with healthy volunteers.
  - TMS training website: <a href="https://">https://</a>
     verifytraining.blogs.auckland.ac.nz/
- Sites should maintain their completed healthy volunteer source documentation (e.g., TMS Safety Checklist) in a binder onsite





# **Optional Drop-In TMS Sessions**

- Occurs weekly on Tuesdays 4-5pm ET. Zoom meeting series have been emailed to sites.
- Purpose is to address questions related to TMS procedure and equipment.
- These sessions are optional. Feel free to drop-in at any session
- A member of our core TMS team will be available to answer questions.

# Practical TMS Training with Healthy Volunteers

### Standard Track Sites

- Each TMS operator needs to upload 5 healthy volunteer datasets that will be quality checked by the VERIFY team.
- This number could potentially be reduced by the TMS team if deemed appropriate!
- The same healthy volunteer can be assessed on different days for separate datasets, but you must submit data from at least 2 and preferably 3 unique healthy volunteers.

#### **Fast Track Sites**

- Each TMS operator needs to upload 2 healthy volunteer datasets that will be quality checked by the VERIFY team.
- These datasets should come from 2 unique healthy volunteers.

### **Study Contacts**

**CIRB- Regulatory contacts:** 

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