

The VERIFY STUDY

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

Newsletter August 2022 Issue 8

Study Enrollment

Congratulations to **MedStar Washington Hospital Center** for enrolling our 1st participant!!

Who will be the next site?!

When your site is released to enroll, this will trigger the startup payment for your site

Key Action Items for Completion of Trainings

- Online Training modules for all study staff
- Practical TMS training on healthy volunteers
 - The last step for fast-track sites to have site readiness calls and be released to enroll!!
- TMS technique check by VERIFY leadership/consultants for standard TMS sites
 - The last step for standard sites to have site readiness calls and be released to enroll!!

TMS Reminders

- TMS Operators need to be given the green light email from the VERIFY team before proceeding with healthy volunteer TMS training.
 - In order to receive this green light email, the TMS Operator needs to successfully complete their 6 online TMS training modules and be listed as a TMS Operator on their site's DOA.
- All TMS operators are to upload their healthy volunteer training certificate in WebDCU under the People Document section. **This is the only TMS training certificate that should be uploaded to WebDCU.**
- 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: <https://verifytraining.blogs.auckland.ac.nz/>
- Sites should maintain their completed healthy volunteer source documentation (e.g., TMS Safety Checklist) in a binder onsite.
- Any study staff can be assigned role of TMS Operator (does not have to be PT/OT)



"Congrats to MedStar for enrolling the study's 1st participant! We look forward to seeing more enrollments and more sites being released to enroll. Thank you for your continued hard work in this important study!"

- Achala Vagal, MD

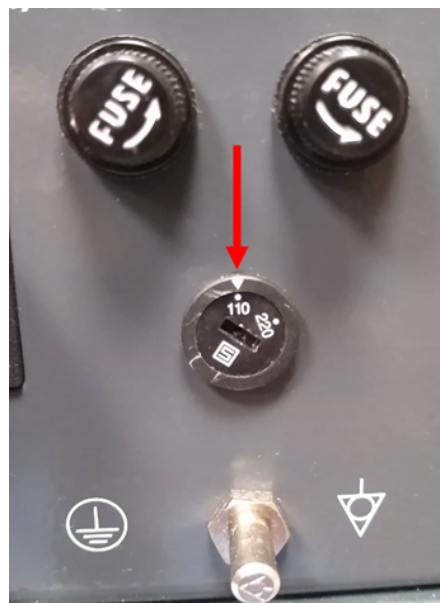
Sites using MEGA-TMS machine

- Please check that switch on back of machine is set to 110V. This will ensure the machine can give stimuli at higher intensities. You may need a small screwdriver to change switch.



- Please note TMS Operators that

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ARAT Kit Updates

- There have been some delays with the vendor shipping the kits. Once kits are received, they will be shipped to sites.
- Please note that sites will not need the ARAT kit until visit 6. So your site can still be released to enroll without having the kit on site.

Ancillary substudy policy

- The ancillary substudy policy is attached for your review.
- Please enroll at least 2 participants at your site before submitting an ancillary/substudy proposal to the VERIFY leadership team.



Study Contacts

CIRB- Regulatory contacts:

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All Other VERIFY questions: Lisa Mundo mundokl@ucmail.uc.edu

The next PI/CRC webinar is on 08.15.2022 from 4pm-5pm ET. Zoom login details have been emailed to sites.

Email QUESTIONS to: verifystudy@ucmail.uc.edu

Race to Activation- First Enrollment

Site Name	CTA Executed	CIRB Approved	DOA Approved	Investigator agreement form's uploaded	TMS Shipping Address entered	TMS Machine obtained	TMS online training Completed	Greenlight to start TMS HV Training	Uploaded TMS HV data to RedCAP	TMS HV Training Completed for at least 1 TMSO	TMS Technique Check	MRI Phantom Approved	All WebDCU Documents uploaded	Site Activation Meeting Completed	Site Activated	July Enrollment
MedStar Washington Hospital Center																1
University of Cincinnati Medical Center																0
Emory University																0
University of Michigan University Hospital																
UT-Memorial Hermann Texas Medical Center																
The University of Utah																
NYU Langone Medical Center - Tisch Hospital																
Medical University of South Carolina (MUSC)																
UPMC Presbyterian Hospital																
UVA Medical Center																
Montefiore Medical Center																
Duke University Hospital																
University of Wisconsin University Hospital																
University of Alabama Hospital																
Massachusetts General Hospital																
Lahey Hospital & Medical Center																
UCSF Medical Center																
Baystate Medical Center																
University of Maryland Medical Center																
University of Texas Southwestern Medical Center																
San Francisco General Hospital																
OSU Wexner Medical Center																
Harborview Medical Center																
University of Iowa Hospitals & Clinics																
Houston Methodist Hospital																
Ronald Reagan UCLA Medical Center																
Pennsylvania Hospital																
Penn State Hershey Medical Center																
Prisma Health Richland Hospital																