

**TRANScranial direct current stimulation for P  
Ost-  
stroke motor Recovery - a phase II sTudy  
(TRANSPORT 2)**

MANUAL OF PROCEDURES MOP

December 2018

## Statement of Work-TRANSPORT 2

Below

Attached

pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a Subrecipient Federal Award Project Description:

### **Clinical Trial Performance Site Locations: 12 sites**

#### **Projected Enrollment: 129 subjects**

Once the subject enrollment accrual is achieved the Principal Investigator will receive notification from the trial database via an email message instructing the site to cease subject enrollment. Subjects cannot be randomized after the email notification is sent will not be considered eligible for payment under the terms of this agreement.

#### **Sites will be retained or placed on probation if:**

- A site does not randomize within 4 months of activation or has 4 months pass without any randomizations at any point in the trial.
- A site has 3 consecutive consented subjects but fails to randomize.

#### **Once a site is on probation the site may be replaced with a back-up site if:**

- No subject randomizations occurs within 3 months after being placed on probation.
- There is non-adherence to the responsibilities listed below.

#### **EACH CLINICAL TRIAL PERFORMANCE SITE WILL BE RESPONSIBLE FOR:**

- Complying with the trial investigational plan as defined in the protocol and approved by the StrokeNet CIRB and the NINDS appointed DSMB
- Compliance with trial specific StrokeNet CIRB informed consent template
- Obtaining appropriate Central IRB and local IRB acknowledgement of CIRB review.
- Reporting of required adverse events to CIRB and to the WebDCU CTMS for central trial review in compliance with defined procedures
- Completion of internal logistics necessary to execute the trial
- Completion of Clinical Trial Agreement
- Documentation of qualified clinical and protocol trained site personnel
- Documentation of qualified human subject protection trained site personnel
- Documenting trial related financial conflict of interest for all site personnel
- Assurance that standard medical care and management of adverse events will be provided for all subjects randomized
- Receipt, storage and accountability of Study provided Devices in compliance with defined procedures
- Handling and administration of study devices and supplies to subjects in compliance with defined procedures
- Complying with all local, and US federal requirements for the initiation and ongoing performance of a clinical trial per the principles of Good Clinical Practice as defined in ICH Consolidated Guidance (ICH E6) and Title 45 and part 46 Federal Policy for the Protections of Human Subjects "Common Rule"
- Assuring that the expenses for research related procedures are not billed to the subject
- Assurance of access to subject medical records for site monitoring visits per institutional and trial procedures.
- Providing a site representative to attend all required investigator meetings and trial conference calls
- Completion of screen failure logs by the 10<sup>th</sup> of the month in the WebDCU™ system
- Data collection entered into WebDCU in a time frame consistent with the MOP.
- Subject data collection entered into WebDCU database within a time frame determined by the WebDCU or 10 business days whichever is greater

- Compliance with all TRANSPORT2 policies and procedures published in the trial MOP. MOP will be available under Project Documents in the WebDCU™ CTMS as maintained by the NDMC and on the StrokeNet website: <http://www.nihstrokenet.org/>
- Responsiveness of site PI or in his/her absence, another designated investigative team member, to email correspondence within 2 business days.

### **Site Start-up Payments**

A non-refundable start-up payment totaling \$5,000 will be made in two incremental payments (inclusive of IRB fees, as applicable) to each participating RCC or Satellite:

- **Payment 1** in the amount of \$2,500 upon full execution of the FDP Fixed Price Research Clinical Trial Agreement; and,
- **Payment 2** in the amount of \$2,500 upon receipt of CIRB approval for Study Start-Up and site study team personnel have Fugl-Meyer certification verification uploaded to the WebDCU™.

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### **Per subject Payment Schedule**

Payments will be made at least quarterly, but not more frequently than once monthly.

After enrollment to one of the study arms, the Maximum per subject payment is \$12,165 + (\$5,109) = \$17,274 total. Indirect costs (42% StrokeNet F&A) shown in parentheses. All payments are contingent on receipt of eCRFs at the relevant study visit.

Payment will be divided into three increments per subject enrolled. Each payment will be inclusive of the 42% StrokeNet F&A where allowed.

#### **Payment One: Baseline & Randomization - \$3,675 (\$1,543) = \$5,218**

- Eligible subject has completed screening and baseline study visits and is randomized
- All data for screening, baseline, and randomization are entered into WebDCU™
- All queries are resolved for the subject
- Subject payment reads "Ready" in WebDCU™

#### **Payment Two: Post-Therapy Sessions - \$5,700 (\$2,394) = \$8,094 – All 10 sessions**

- Proration of the payment will be based on the number of completed sessions, \$570 will be paid for each session.
- All data for study visits are entered into WebDCU™
- All queries are resolved for the subject
- Subject Post Therapy payment reads "Ready" in WebDCU™

#### **Payment Three: End of Study - \$2,790 (\$1,172) = \$3,962**

- Subject is not lost to follow up
- Completes all requirements for Post Therapy - 1 day Follow Up, 1 month Follow Up, and 3 month Follow Up
- All data for study visits are entered into WebDCU™
- All queries are resolved for the subject
- Subject payment reads "Ready" in WebDCU™

## Schedule of Events

Events/Assessments	Screening visit	Baseline & Randomization visit	Sessions 1-10	F/U 1 (15 days)	F/U 2 (45 days)	F/U 3 (105 days)	TOTAL
Eligibility criteria, study information	X						
Demographics, Medical History, Concomittant Meds	X						
Informed Consent	X						
Randomization		X					
Therapist baseline visit		X					
Coord baseline visit			X				
Daily CIMT (OT for therapy, coordinator for videotaping)			X				
tDCS safety questionnaire	X	X	X				
NIHSS		X					
FM-UE	X	X		X	X	X	
WFMT		X		X	X	X	
MoCA		X		X	X	X	
mRS	X			X	X	X	
SIS-16		X		X	X	X	
TMS		X		X			
TMS (60 min)		X		X			
MR Scan		X		X			
MR Scan (60 min)		X		X			
Screen failure + videotaping	X						
Room fee (\$80/hr, 3hrs)	X	X	X	X	X	X	
Pt reimbursement	X	X	X	X	X	X	
<b>Direct Costs</b>		3,675	5,700			2,790	12,165
<b>Indirect Costs</b>		1,543	2,394			1,172	5,109
<b>Subtotals</b>		<b>\$ 5,218.00</b>	<b>\$ 8,094.00</b>			<b>\$ 3,962.00</b>	<b>\$ 17,274.00</b>

See Manual of Procedures (“MOP”), Statement of Work and Payment Schedule.

The MOP can be found at the following URL: [TRANSPORT 2 MOP](#)