ARCADIA PAYMENT SCHEDULE MOP

August 3, 2020

Attachment 5
Fixed Price Clinical Trial Subaward Agreement

Statement of Work **Indirects** **Payment Schedule**

Statement of Work
Below ☒or Attached ☐ __pages
If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Clinical Trial Performance Site Locations: Up to 200 sites

Projected Enrollment: 1,100 subjects

1) Once the subject enrollment accrual is achieved (current cap is 1,100), the performance site Principal Investigator will receive notification via an email message instructing them to cease subject enrollment. Subjects enrolled 24 hours after the email notification is sent will not be considered eligible for payment under the terms of this agreement.

2) Sites that do not randomize a subject within 3 months of activation will be placed on probation.

3) Once a site is on probation, if no subject randomization occurs in the next 3 months, the site could be replaced with a "back-up" site.

4) Sites may also be put on probation if three consecutive patients who meet randomization criteria, based on screening biomarkers, fail to be randomized.

5) Sites may also be put on probation if they fail to adhere to the responsibilities listed below.

EACH CLINICAL TRIAL PERFORMANCE SITE WILL BE RESPONSIBLE FOR:

1) Complying with the trial investigational plan as defined in the protocol and approved by the StrokeNet or VA CIRB and the NINDS appointed DSMB
2) Obtaining appropriate Central IRB review and approval for the performance site.
3) Reporting of required serious adverse events to CIRB and to the WebDCU CTMS for central trial review in compliance with defined procedures
4) Completion of internal logistics necessary to execute the trial (including processes for central core lab shipment or transfer of ECGs and echocardiogram data and blood samples for NT-proBNP assays)
5) Completion of Protocol Trial Agreement
6) Documentation of qualified clinical and protocol trained site personnel
7) Documentation of qualified human subject protection trained site personnel
8) Documenting trial related financial conflict of interest for appropriate site personnel
9) Assurance that standard medical care and management of adverse events will be provided for all subjects randomized
10) Receipt, storage and accountability of study drug in compliance with defined procedures
11) Handling and Administration of Study drug to subjects in compliance with defined procedures
12) 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"
13) Assuring that the expenses for research related procedures are not billed to the subject
14) Assurance of access to subject medical records for site monitoring visits per institutional and trial procedures
15) Providing a site representative to attend all required investigator meetings and trial conference calls
16) Completion of screen failure logs by the 10th of the month in the WebDCU™ system
17) Subject data collection entered into WebDCU database within a time frame determined by the WebDCU or 10 business days whichever is greater
18) Compliance with all ARCADIA policies and procedures published in the trial MOP, which will be available under Project Documents in the WebDCU™ CTMS as maintained by the NDMC.

Indirect Information

Indirect Cost Rate (IDC) Applied 42 % ☐ TDC, or ☐ MTDC, or ☒ OTHER

1) A uniform institutional allowance was determined by the NCC for F&A recovery and was applied to applicable cost elements within each fixed unit per patient cost.

2) The NIH StrokeNet used the 25 Regional Coordinating Center on campus and off campus rates. Determined an average of each and averaged those two numbers which came out to 42%.

3) This is a fixed fee per patient clinical trial. All fixed price (fee) units will be inclusive of F & A costs recovery.

ARCADIA PAYMENT SCHEDULE (25-June-2019)

1) Trial specific per-patient budgets are defined as research related costs with payment amounts that will be non-negotiable. There is no F&A paid on any items marked Standard of Care on the attached Schedule of Events.
2) Payments will be made at least quarterly but may be more frequent.
3) NCC retains the right to review and question data identified below for completeness.
4) NCC prior to closeout will verify final payment.

SITE START-UP PAYMENTS.

A one-time non-refundable start-up payment will be made in the amount of $2,000 to each StrokeNet site when the site is released to enroll in WebDCU™.

SUBJECTS ENROLLED AND ALL REQUIRED FOLLOW-UP VISITS COMPLETED

Minimum subject participation is 18 months and the maximum is 48 months. Indirect costs (42% StrokeNet F&A) shown in parentheses. All Payments are contingent on receipt of CRFs for all relevant data points.

The maximum payment for any single subject would be $7260. ($3049.) =$10,309. This would include *all* 48 months of follow-up visits and the Study Close-out visit.

The minimum payment for a single subject would be $4260. ($1789.) =$6049.
This would include 18 months of follow-up visits and the Study Close-out visit.

Payment will be divided into the following increments. Each payment will be inclusive of the 42% StrokeNet F&A.

Payment 1. Consent, Screening and Enrollment: $1188.00 ($499.) =$1687.
All Payments after receipt and verification of all required eCRFs data and *all* required screening assessments to central core facilities unless waived by the trial PI.

Payment 2. Payment for 30 day (**$299.00)** done as a telephone *or* in-person visit and the 3 month in person visit **($495)** will be made at the completion of the 3 month visit and submission of cRFs. Total interval payment **$794 ($333.)= $1127.**

Payment 3- 6 month visit payment will be **$514. + ($216.) = $730.**

Payment 4- 9 month visit payment will be **$495. + ($208.) = $703.**

Payment 5- 12 month visit payment will be **$586. + ($246.) =$832.**

Payment 6- 18 month visit payment will be **$607. + ($255.) =$862.** This payment is inclusive the 15 month telephone assessment call.

Payments 7 through 17- 24 through 84 month visits will be **$600. + ($252.) =$852.** These payments are inclusive of the previous 3 month telephone assessment call.

Final Payment - (at study closeout or 30 after end of study drug) **at any point in the trial will be $76. + ($32.) = $108.**

CORE LAB ELIGIBILITY SCREEN FAILURES - Those subjects who qualify for all inclusion and exclusion criteria and are consented but who **fail** to qualify based on central analyses of atrial cardiopathy biomarkers:

Payment **$300** per subject -Payments will be made after receipt and verification of all required eCRFs data and all required screening assessments to central core facilities. No payment will be made if central labs data is not complete unless waived by the trial PI.

***Payment is inclusive of previous interim telephone assessment tasks/CRFs.**