Statement of Work-ARCADIA-CSI

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: 108 sites

Projected Enrollment: 500 subjects

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

Sites will be retrained or placed on probation if:

- Primary trial ARCADIA determines the need
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Once a site is on probation the site may be replaced with a back-up site if:

- Primary trial ARCADIA determines the need

EACH CLINICAL TRIAL PERFORMANCE SITE WILL BE RESPONSIBLE FOR:

- Complying with the study investigational plan as defined in the protocol and approved by the StrokeNet CIRB and the NINDS appointed DSMB
- Compliance with study 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 study
- Completion of Clinical Trial Agreement
- Documentation of qualified clinical and protocol trained site personnel
- Documentation of qualified human subject protection trained site personnel
- Documenting study 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
- Complying with all local, and US federal requirements for the initiation and ongoing performance of a clinical study 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 study procedures.
- Providing a site representative to attend all required investigator meetings and study conference calls
- Entering screen failure data in WebDCU™ within 5 days of screening
- Data collection entered into WebDCU in a time frame consistent with the MOP
- Compliance with all ARCADIA-CSI policies and procedures published in the study MOP. MOP will be available under Project Documents in the WebDCU™ CTMS and some sections may be posted 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

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 29 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.

4. Clinical trial performance sites will not submit invoices to the NCC for any study activities completed. Payments for subject enrollment and other interval payments will be determined automatically for all milestone/tasks completed as confirmed by the WebDCU™ and StrokeNet NCC.

Site Start-up Payments

A one-time non-refundable start-up payment totaling $500 will be made (inclusive of IRB fees, as applicable) to each participating RCC or Satellite:

- **Payment 1** - Start-up payment is marked as ready to be paid when the site enrolls their first subject in WebDCU™.

Per subject Payment Schedule

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

The Maximum per subject payment is $2997 + ($1,259) = $4,256 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 - $281 + ($118) = $399 or $1,367* + ($574) = $1,941**

- Eligible subject has completed screening and baseline study requirements
- All data for screening, baseline are entered into WebDCU™
- All queries are resolved for the subject
- Subject payment reads “Ready” in WebDCU™
- * Only if participant requires MR imaging (ie. if no MR imaging was done at time of stroke and was done solely for ARCADIA-CSI)

Payment Two: Year 1 - $169 + ($71) = $240

- All data for study visits are entered into WebDCU™
- All queries are resolved for the subject
- Subject Year 1 payment reads “Ready” in WebDCU™

Payment Three: Year 2 - $169 + ($71) = $240

- Completes all requirements for Year 2
- All data for study visits are entered into WebDCU™
- All queries are resolved for the subject
- Subject payment reads “Ready” in WebDCU™

<u>Payment Four</u>: Year 3 or End of-Study - $1,292 + ($543) = $1,835

- Subject is not lost to follow up
- Completes all requirements for Year 3
- Payment will be pro-rated if the 3 year MRI is not done
- All data for study visits are entered into WebDCU™
- All queries are resolved for the subject
- Subject payment reads “Ready” in WebDCU™