conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Protocol Deviation** ☒ **Source** ☐ **Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Note: Please complete only one deviation per form.   *PD # in EDC _____*

Date of Deviation	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Date of Site Awareness	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Time Period of Deviation	☐ Screening ☐ Index Procedure ☐ Discharge ☐ Day 7 ☐ Day 45 ☐ 6 Months ☐ 12 Months ☐ 18 Months ☐ 2 Year ☐ 3 Year ☐ 4 Year ☐ 5 Year ☐ Not related to a study visit ☐ Unscheduled visit
Deviation Category *(Select one)*	☐ Eligibility ☐ Adverse event not reported per protocol ☐ Informed Consent ☐ Randomization ☐ Study medications ☐ Procedure/assessment complete out of window ☐ Procedure/assessment done but not per protocol ☐ Procedure/assessment incomplete or not done ☐ Visit not done ☐ Visit out of window ☐ Other, specify: _____
If procedure/assessment *(Check all that apply)*	☐ Study Index Procedure ☐ Physical Exam ☐ Angiography ☐ Echocardiography/CT ☐ ECG ☐ Laboratory Assessment ☐ NIHSS ☐ mRS ☐ QVSFS ☐ Other, specify: _____

Deviation Reason	☐ Oversight in protocol requirements ☐ Subject refusal or non-compliance ☐ Unable to reach subject ☐ Site scheduling difficulty/error ☐ Investigator decision to protect the rights, safety and welfare of subject ☐ Equipment failure ☐ User error ☐ COVID-19 – Subject diagnosed ☐ COVID-19 – Other, specify: _____ ☐ Disaster/Weather related ☐ Other, specify: _____
Additional Description of Deviation	
Action Taken	☐ None ☐ Documented site retraining ☐ Subject education/review of study requirements with subject ☐ Other, specify: _____
Does this Protocol Deviation (PD) require prompt reporting to the IRB?	☐ Yes ☐ No
	If yes, submitted on: __ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)

_____   __ __ / __ __ __ / __ __ __ __

Site Personnel Signature   **Date (DD/MMM/YYYY)**