INVESTIGATOR CRF

Possible Transient Ischemic Attack (TIA) or Stroke Event

Date and time of event onset	____ / ____ / ____ ___:___	The date and time of stroke onset are often difficult to determine. The accuracy required for the stroke onset time is trial specific. The clinical note that accompanies the stroke event should serve as the source of the time of stroke onset.
Type of Event	❍ **TIA** ❍ **Stroke - Type Ischemic** ❍ **Stroke - Type Hemorrhagic** ❍ **Stroke - Type Undetermined** ❍ **Not a TIA or Stroke**	Clinical determination of stroke event. Check only one. The clinical note that accompanies the stroke event should serve as the source of the event type.
Narrative (Brief description of clinical characteristics, supportive imaging or other laboratory findings, and clinical impression or diagnosis documented by clinician in medical record)	**(Enter Text - Should Correspond to Medical Record)**	The clinical narrative is an open text field that is a summary of a note written by a physician in the patient's medical record. The obligation to write such a note resides with the clinical site investigator if no other physician does so. The note will describe the 1) onset of the stroke event or the circumstances that indicated a stroke occurred, 2) the estimated time of stroke onset, 3) the clinical signs observed, and 4) the results of any laboratory investigations or clinical studies that were performed. The note will conclude with a diagnosis and an explanation any unusual aspects of the case. If the ultimate diagnosis is "Not a TIA or Stroke" these guidelines should still be followed for the possibl e stroke event.

Disability Measurement

Date and time of assessment	____ / ____ / ____ ___:___
Modified Rankin Score	❍ **0 - No Symptoms at all** ❍ **1 - No significant disability despite symptoms; able to carry out all usual duties and activities** ❍ **2 - Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance** ❍ **3 - Moderate disability; requiring some help, but able to walk without assistance** ❍ **4 - Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance** ❍ **5 - Severe disability; bedridden, incontinent and requiring constant nursing care and attention** ❍ **6 - Dead**

CEC CRF

Possible Transient Ischemic Attack (TIA) or Stroke Event

Date and time of event onset	____ / ____ / ____ ___:___	Same as above.
Type of Event	❍ **TIA** ❍ **Stroke - Type Ischemic** ❍ **Stroke - Type Hemorrhagic** ❍ **Stroke - Type Undetermined** ❍ **Not a TIA or Stroke**	CEC determination of event type.
Event Confirmed by Adequate Narrative	❍ **Yes** ❍ **No**	Check yes if the CEC agrees that both 1) the clinical note is adequate and 2) the diagnosis is supported by the observations and test results reported in the note. Otherwise check no.
Narrative (Brief description of clinical characteristics, supportive imaging or other laboratory findings, or other relevant data that result in disagreement with Type of Event coded on Investigator CRF)	**(Enter Text)**	The narrative is an open text field to be used when the CEC disagrees with the event type determination of the investigator or when the CEC wishes to document additional issues. It should always be completed if the CEC checks "no" in the field above and is optional otherwise.

Disability Measurement

Date and time of assessment	____ / ____ / ____ ___:___
Modified Rankin Score	❍ **0 - No Symptoms at all** ❍ **1 - No significant disability despite symptoms; able to carry out all usual duties and activities** ❍ **2 - Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance** ❍ **3 - Moderate disability; requiring some help, but able to walk without assistance** ❍ **4 - Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance** ❍ **5 - Severe disability; bedridden, incontinent and requiring constant nursing care and attention** ❍ **6 - Dead**