<<SITE NAME>> to study experimental stroke drug

<<SITE NAME>> will conduct a multi-centered, randomized, Phase 3 research study to learn if the experimental drug recombinant Factor VIIa (rFVIIA), a protein that our body makes, can be used to decrease bleeding in the brain of patients who suffer sudden bleeding in the brain, also called intracerebral hemorrhage (ICH).

The study entitled *"Recombinant Factor VIIa (rFVIIa) for Acute Hemorrhagic Stroke Administered at Earliest Time",* also referred to as the FASTEST trial, is funded by the National Institutes of Health (NIH). The research will be conducted at <<SITE SPECIFIC>>. Participants in the clinical trial will receive either the experimental drug rFVIIa or a placebo (no active ingredient), and the best standard medical care.

ICH accounts for more than 10% of the estimated 17 million strokes worldwide each year and is the deadliest type of stroke with a mortality rate of more than 40%. Currently, there is no effective treatment for ICH.

<< INSERT SITE SPECIFIC QUOTE or use quote from Dr. Broderick >> "Intracerebral hemorrhage, the most deadly type of stroke, occurs when a diseased blood vessel within the brain bursts, causing blood to leak inside the brain creating pressure and potential damage to brain cells," said Dr. Joseph Broderick, MD, FASTEST Principal Investigator. "Currently, there is no scientifically proven treatment for intracerebral hemorrhage. Our hope is that rFVIIa, if administered within two hours of an intracerebral hemorrhage, will result in decreased bleeding as compared to placebo and improve outcome."

Commented [DJ(1]: Quote from Dr. Broderick, useable across all sites OR spot is open for a site specific quote that is submitted to ADVARRA with site specific EFIC plan.

The study will include adults from 18 through 80 years old with spontaneous bleeding in the brain, ICH. The study medicine will be given within two hours of stroke onset. Because acute ICH is a life-threatening condition requiring immediate treatment, some patients will be enrolled without consent if unconscious or a family member or other representative is not readily available. Every attempt will be made to locate family prior to enrollment to allow them to decide about the patient's participation in the study.

Before the study starts at <<SITE NAME>>, one of the requirements to be a participating site is to engage in community outreach efforts to provide information, answer questions and get community members' input about this important clinical research. <<SITE NAME>>, will be reaching out to community members to gain as much input as possible.

<< INSERT SITE SPECIFIC QUOTE if a second quote included in site EFIC plan to ADVARRA >>

For more information about the research study, <<INSERT SITE SPECIFIC WAY TO CONTACT AND /OR METHOD TO ACCESS STUDY SURVEY>>

<<Insert QR code or https://redcap.link/FASTEST >>

or contact << Principal investigator, and the study team at <<Site email>>.