Enrollment and Randomization Form

Name: _____ MRN: _____

Age:_____ Sex:_____ DOB:_____/_____/_____ Race:_____ Ethnicity:_____

Inclusion Criteria

- ☐ Acute Ischemic stroke
- ☐ Treated with 0.9mg/kg IV rt-PA within 3 hours of stroke onset or time last known well
- ☐ Age ≥ 18
- ☐ NIHSS score ≥ 6 prior to IV rt-PA
- ☐ Able to receive assigned study drug within 60 minutes of initiation of IV rt-PA

Exclusion Criteria

- ☐ Known allergy or hypersensitivity to argatroban or eptifibatide
- ☐ Previous stroke in the past 90 days
- ☐ Clinical presentation suggested a subarachnoid hemorrhage, even if initial CT scan was normal
- ☐ Surgery or biopsy of parenchymal organ in the past 30 days
- ☐ Trauma with internal injuries or ulcerative wounds in the past 30 days
- ☐ Severe head trauma in the past 90 days
- ☐ Systolic blood pressure >180mmHg post-IV rt-PA
- ☐ Diastolic blood pressure >105mmHg post-IV rt-PA
- ☐ Serious systemic hemorrhage in the past 30 days
- ☐ Known hereditary or acquired hemorrhagic diathesis, coagulation factor deficiency, or oral anticoagulant therapy with INR >1.5
- ☐ Positive urine pregnancy test for women of child bearing potential
- ☐ Glucose <50 or >400 mg/dl
- ☐ Platelets <100,000/mm3
- ☐ Hematocrit <25 %
- ☐ Elevated PTT above laboratory upper limit of normal
- ☐ Creatinine > 4 mg/dl
- ☐ Ongoing renal dialysis, regardless of creatinine
- ☐ Received Low Molecular Weight heparins (such as Dalteparin, Enoxaparin, Tinzaparin) in full dose within the previous 24 hours
- ☐ Abnormal PTT within 48 hours prior to randomization after receiving heparin or a direct thrombin inhibitor (such as bivalirudin, argatroban, dabigatran or lepirudin)
- ☐ Received Factor Xa inhibitors (such as Fondaparinaux, apixaban or rivaroxaban) within the past 48 hours
- ☐ Received glycoprotein IIb/IIIa inhibitors within the past 14 days
- ☐ Pre-existing neurological or psychiatric disease which confounded the neurological or functional evaluations e.g., baseline modified Rankin score >3
- ☐ Other serious, advanced, or terminal illness or any other condition that the investigator felt would pose a significant hazard to the patient if rt-PA, eptifibatide or argatroban therapy was initiated
  - ☐ Example: known cirrhosis or clinically significant hepatic disease
- ☐ Current participation in another research drug treatment protocol - Subjects could not start another experimental agent until after 90 days
- ☐ Informed consent from the patient or the legally authorized representative was not or could not be obtained
- ☐ High density lesion consistent with hemorrhage of any degree
- ☐ Large (more than 1/3 of the middle cerebral artery) regions of clear hypodensity on the baseline CT Scan. Sulcal effacement and/or loss of grey-white differentiation alone are not contraindications for treatment

Stroke onset/ LKN

Date:_____/_____/_____

Time:_____:_____

Scores on Hospital Admission

Pre-Morbid mRS: _____ (>3 S/F)

NIHSS: _____ (<6 **prior** to tPA S/F)

Lab Values

Glucose: _____ (<50 or >400 mg/dl S/F)

Hematocrit: _____ (<25% S/F)

Platelet Count: _____ (<100,000/mm3 S/F)

Creatinine: _____ (>4 mg/dl S/F)

24/7 hotline: 1-833-229-6678 (MOST)

STUDY DRUG ORDERING INFO:

1. Call inpatient pharmacy to alert them of a potential study patient: **215-662-2907. ASK TO SPEAK TO IV PHARMACIST.**

2. Search "MOST" in order sets and select the appropriate arm to order study drug.

3. Open up drug orders and add subject number and dose, provided to you on the WebDCU Randomization Verification form. Also add kit number in the "Note to Pharmacy" free text.

Note: Drug is located in inpatient pharmacy in the following places:

ARGATROBAN and **PLACEBO** kits are stored room temperature in the IDS cabinet in the IV room, right next to the oral medication compounding area

EPTIFIBATIDE is located in the IDS refrigerator, to the right of the IV room.

Signature_____ Date_____