

Enrollment and Randomization Checklist-PAH

Screening (pre-randomization)

- ☐ Informed consent
- ☐ Review inclusion/exclusion criteria and document on CRF
- ☐ Local labs
 - ☐ CMP
 - ☐ Heme/CBC (**platelets not needed for randomization, but must be resultd prior to drug admin!**)
 - ☐ Coags (only if patient is taking an anticoagulant)
 - ☐ Urine pregnancy test if of child bearing potential
- ☐ **Obtain subject weight:** _____ kg
- ☐ Baseline (pre-stroke) mRS: _____
- ☐ NIHSS: _____
- ☐ Obtain the following from RAPID imaging for randomization:
 - ☐ Ischemic Core Volume: _____ mL
 - ☐ Mismatch ratio: _____
 - ☐ Mismatch volume: _____ mL

Randomization

- ☐ Call inpatient pharmacy and ask to speak to the IV pharmacist to alert them so they can begin to prepare: 215-829-3246
- ☐ Log into Endpoint: <https://secure.endpointclinical.com/>
 - Follow these steps in order to randomize:
 - Click on **IWR** drag down under Genentech logo, and select **screening**
 - After screening information is complete, go back to IWR drag down and select **randomization** to complete randomization process
 - **MAKE SURE THE APPROPRIATE SITE IS SELECTED!**
 - Print randomization with kit assignment and fax to pharmacy: 215-829-5475
- ☐ Place order in EPIC for study drug- please refer to separate document with instructions
- ☐ Obtain study drug and administer to patient

KEY TIME POINTS TO KNOW!

1. Randomization **MUST** occur within 90 minutes of qualifying brain imaging. If the elapsed time between imaging and randomization exceeds 90 minutes, repeat imaging must be obtained before proceeding with study enrollment.
2. **STUDY DRUG MUST BE ADMINISTERED PRIOR TO GROIN PUNCTURE!**
3. Following study drug administration, neurologic assessments and vital signs should mirror post-tPA administration (Every 15 minutes for first 2 hours, then every 30 minutes for 6 hours, then hourly until 24 hours post administration)

Emergency contacts:

Endpoint support: 877-810-4786

Hotline: 1-888-316-3335

RAPID: 650-388-9767, ext 2

HUP site number: 317790

PAH site number: 319158

PPMC site number: 319156