

## SO YOU CONSENTED SOMEONE INTO SHINE...WHAT NOW?

### *An Investigator's Guide @ SUNY Downstate*

1. Make 3 additional copies of the consent form, and distribute as listed below:
  - a. Original – keep for research record
  - b. Copy 1 – Medical Record
  - c. Copy 2 – Patient/Patient's Family
  - d. Copy 3 – Pharmacy
2. Randomize patient into WebDCU.
  - a. Go to: <https://webdcu.musc.edu/nett/login.asp>
  - b. Select "SHINE" from the "Project" drop down menu and enter your log-in information.
  - c. Enter the date under "Add New Subject" on the main page, and click "Add Subject". Make sure you have the correct site selected.
  - d. Complete Eligibility and NIH Stroke Scale CRFs first.
    - i. To enter data, click on the white paper icon to the right.
    - ii. Once data is entered, click save on the bottom, and then "Submit CRF" on the top.
    - iii. Remember, NIH Stroke Scale **must** be done within 30 minutes of randomization by a certified investigator.
    - iv. Before randomization, ensure there are no Rule Violations or Errors on the NIHSS or Eligibility CRFs (white papers should now have lines and green check marks; **they should not be red**).
  - e. Complete Randomization CRF, click save record, and make sure you submit CRF.
    - i. Print a copy of the randomization confirmation, or save a screen shot (to capture, press Ctrl + Print Screen), and paste into a Word or Paint document.
3. Page (917-760-1653) or call (646-261-5730) Dr. Spiro Demetis to let him know we have enrolled a SHINE patient. He will facilitate ICU assistance.
4. Make sure that the patient gets registered in Eagle (orders in ER Holding **NOT** Outpatient). Call admitting to check on status/progress : (718) 270-2862
5. Order the appropriate SHINE order set for the patient in HealthBridge – Either Intervention or Control arm orders. Please see supplemental SHINE ordering instructions on Clinical Monster.
6. Fax copies of the consent, randomization confirmation, and orders to the Research Pharmacy (**x8192**) from 7 am-3 pm Monday to Friday, or the main pharmacy (**x2855**) at all other hours.
7. Get the SHINE laptop.
  - a. Turn on the laptop.
  - b. Open Internet Explorer, go to [www.downstate.edu](http://www.downstate.edu).
  - c. It will redirect you to a site to login, click that you accept the certificate.
  - d. Login as [steven.levine@downstate.edu](mailto:steven.levine@downstate.edu)
  - e. When it says that you are successfully logged in, click on the SHINE icon on the desktop.
  - f. Once the drug arrives, enter patient into SHINE study platform.
    - i. Make sure you click on the arm that matches the randomization confirmation.
8. Complete research intake form and schedule follow-up appointments.
9. Follow Protocol, and make sure a study team member is present for patient transfer to the ICU.

### FOR ANY ISSUES CALL:

Randomization Issues: WebDCU Emergency Hotline at **1-866-450-2016**

Clinical Issues/Concerns: SHINE Emergency Hotline at **1-800-915-7320**