

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

An Investigator's Guide @ KCHC

1. Make 3 additional copies of the consent form, and distribute as listed below.
 1. Original – keep for research record
 2. Copy 1 – Medical Record
 3. Copy 2 – Patient/Patient's Family
 4. 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".
 - 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. Order the appropriate SHINE order set for the patient in Quadramed– Either Insulin or Saline drip and corresponding orders.
4. Order diet of 60 g carbohydrate/meal
5. Deliver copies of the consent, randomization confirmation, and orders to the Research Pharmacy (**x3748**) from 8 am - 4 pm Monday to Friday, or the B pharmacy (**x**) at all other hours (C Level, closest to elevators between ED and C Building).
6. Fax diet confirmation to Nutrition (718-245-4345, 718-613-8017) using cover sheet located on Clinical Monster and in the research binder.
7. Get the SHINE laptop, currently stored in the ED offices. Lock laptop to the cart.
 - a. Turn on the laptop.
 - b. Enter your KCHC Windows credentials to login to the computer.
 - c. When it says that you are successfully logged in, click on the SHINE icon on the desktop.
 - d. 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**