Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

Preparing Study Orders & Laptops

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SHINE Project Director

SHINE

Pharmacy Plan Overview

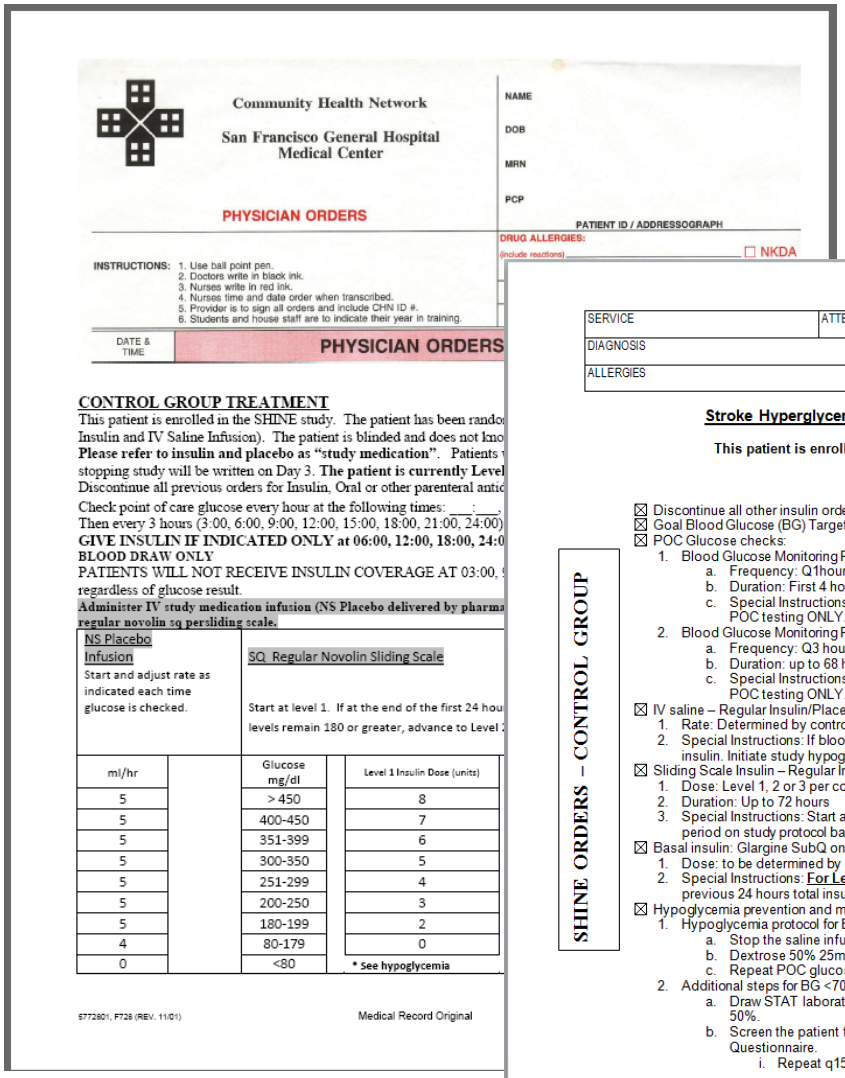
- Pharmacy Plan Summary
  - Study treatments on formulary & storage
  - Procedure for randomization
  - Process for ordering and dispensing
  - Naming and labels
- Study Orders
  - Medication
  - Communication/Physician to nurse orders

Study Treatments

	Control Group	Intervention Group
IV Infusion	**Normal saline** *0.9% sodium chloride* [Rate per Control Treatment Screen]	**Human regular insulin** *Humulin R, Novolin R* [Rate per GlucoStabilizer®]
SQ Injections	**Human regular insulin** *Humulin R, Novolin R* [Rate per Control Treatment Screen] AND **Basal insulin (Level 3 only)** *glargine (Lantus)* [40% previous 24 hr total insulin requirement]	**Rapid acting analog insulin** *Lispro (Humalog), aspart (Novolog) or glulisine (Apidra)* [Dose per GlucoStabilizer®] OR **Normal saline** *0.9% sodium chloride* [0.05mL at ~0900/2100]
D50	***Dextrose 50% in water*** [25mL (½ amp) slow IV push q 15min BG<80mg/dL]	***Dextrose 50% in water*** [Dose per GlucoStabilizer®]

Communication/Physician to Nurse Orders

- Protocol must be documented
  - POC glucose checks
  - Meals
    - 60 gram CHO diet
    - After check/SQ dose (control group)
    - Assess consumption (intervention group)
  - Hypoglycemia & severe hypergycemia protocol
- Consider including
  - Pausing, interruptions, discharge, HbA1c, daily NIHSS



Community Health Network

San Francisco General Hospital
Medical Center

PHYSICIAN ORDERS

NAME
DOB
MRN
PCP
PATIENT ID / ADDRESSOGRAPH
DRUG ALLERGIES:
(include reactions) ☐ NKDA

INSTRUCTIONS: 1. Use ball point pen.
2. Doctors write in black ink.
3. Nurses write in red ink.
4. Nurses time and date order when transcribed.
5. Provider is to sign all orders and include CHN ID #.
6. Students and house staff are to indicate their year in training.

DATE & TIME | PHYSICIAN ORDERS

CONTROL GROUP TREATMENT

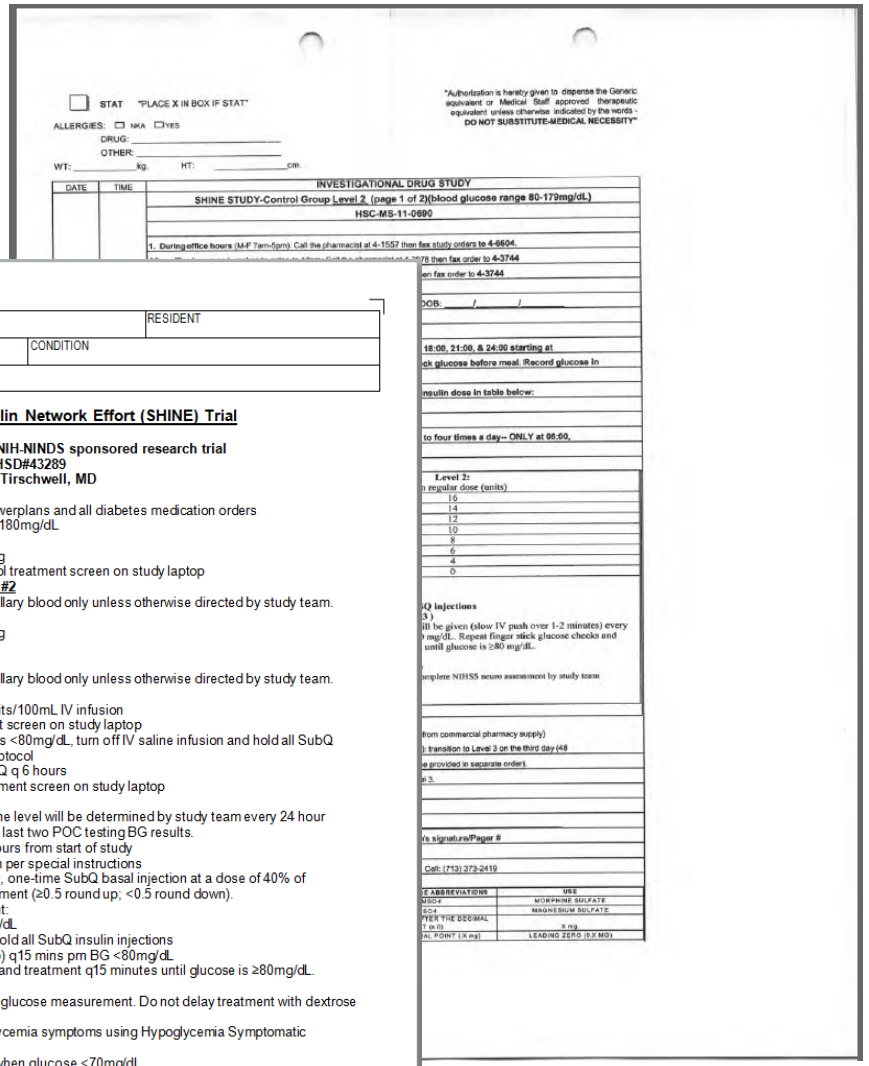
This patient is enrolled in the SHINE study. The patient has been rando
Insulin and IV Saline Infusion). The patient is blinded and does not kno
Please refer to insulin and placebo as "study medication". Patients
stopping study will be written on Day 3. **The patient is currently Level**
Discontinue all previous orders for Insulin, Oral or other parenteral antic

Check point of care glucose every hour at the following times: ___:___;
Then every 3 hours (3:00, 6:00, 9:00, 12:00, 15:00, 18:00, 21:00, 24:00)
GIVE INSULIN IF INDICATED ONLY at 06:00, 12:00, 18:00, 24:0
BLOOD DRAW ONLY
PATIENTS WILL NOT RECEIVE INSULIN COVERAGE AT 03:00,
regardless of glucose result.
Administer IV study medication infusion (NS Placebo delivered by pharma
regular novolin sq persliding scale.

NS Placebo Infusion	SQ Regular Novolin Sliding Scale
Start and adjust rate as indicated each time glucose is checked.	Start at level 1. If at the end of the first 24 hou levels remain 180 or greater, advance to Level

ml/hr	Glucose mg/dl	Level 1 Insulin Dose (units)
5	> 450	8
5	400-450	7
5	351-399	6
5	300-350	5
5	251-299	4
5	200-250	3
5	180-199	2
4	80-179	0
0	<80	* See hypoglycemia

5772801, F728 (REV. 11/01) Medical Record Original



☐ STAT "PLACE X IN BOX IF STAT"

ALLERGIES: ☐ NKA ☐ YES
DRUG: _____
OTHER: _____
WT: _____kg. HT: _____cm.

"Authorization is hereby given to dispense the Generic equivalent or Medical Staff approved therapeutic equivalent unless otherwise indicated by the words - DO NOT SUBSTITUTE-MEDICAL NECESSITY"

DATE	TIME	INVESTIGATIONAL DRUG STUDY
		SHINE STUDY-Control Group Level 2 (page 1 of 2)(blood glucose range 80-179mg/dL)
		HSC-MS-11-0690

1. During office hours (M-F 7am-5pm): Call the pharmacist at 4-1557 then fax study orders to 4-6604.
2. [illegible] then fax order to 4-3744
3. [illegible] then fax order to 4-3744

DOB: ___/___/___

18:00, 21:00, & 24:00 starting at
ck glucose before meal. Record glucose in
insulin dose in table below:
to four times a day-- ONLY at 06:00,

Level 2:
n regular dose (units)
16
14
12
10
8
6
4
0

Q injections
3)
ill be given (slow IV push over 1-2 minutes) every
mg/dL. Repeat finger stick glucose checks and
until glucose is ≥80 mg/dL.
mplete NIHSS neuro assessment by study team
from commercial pharmacy supply)
): transition to Level 3 on the third day (48
e provided in separate order).
el 3.
's signature/Pager #
Cell: (713) 373-2419

E ABBREVIATIONS	USE
MSO4	MORPHINE SULFATE
SO4	MAGNESIUM SULFATE
TYER THE DECIMAL T (X.0)	X mg
AL POINT (X mg)	LEADING ZERO (0.X MG)

SERVICE	ATTENDING	RESIDENT
DIAGNOSIS	CONDITION	
ALLERGIES		

Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

This patient is enrolled in an NIH-NINDS sponsored research trial
UW HSD#43289
PI: David Tirschwell, MD

SHINE ORDERS – CONTROL GROUP

☒ Discontinue all other insulin orders and powerplans and all diabetes medication orders
☒ Goal Blood Glucose (BG) Target Range: <180mg/dL
☒ POC Glucose checks:
1. Blood Glucose Monitoring POC testing
   a. Frequency: Q1hour per control treatment screen on study laptop
   b. Duration: First 4 hours – **then #2**
   c. Special Instructions: Use capillary blood only unless otherwise directed by study team. POC testing ONLY.
2. Blood Glucose Monitoring POC testing
   a. Frequency: Q3 hours.
   b. Duration: up to 68 hours.
   c. Special Instructions: Use capillary blood only unless otherwise directed by study team. POC testing ONLY.

☒ IV saline – Regular Insulin/Placebo 100 units/100mL IV infusion
1. Rate: Determined by control treatment screen on study laptop
2. Special Instructions: If blood glucose is <80mg/dL, turn off IV saline infusion and hold all SubQ insulin. Initiate study hypoglycemia protocol

☒ Sliding Scale Insulin – Regular Insulin SubQ q 6 hours
1. Dose: Level 1, 2 or 3 per control treatment screen on study laptop
2. Duration: Up to 72 hours
3. Special Instructions: Start at Level 1 the level will be determined by study team every 24 hour period on study protocol based on the last two POC testing BG results.

☒ Basal insulin: Glargine SubQ once at 48 hours from start of study
1. Dose: to be determined by study team per special instructions
2. Special Instructions: **For Level 3 only**, one-time SubQ basal injection at a dose of 40% of previous 24 hours total insulin requirement (≥0.5 round up; <0.5 round down).

☒ Hypoglycemia prevention and management:
1. Hypoglycemia protocol for BG <80mg/dL
   a. Stop the saline infusion and hold all SubQ insulin injections
   b. Dextrose 50% 25mL (1/2 amp) q15 mins prn BG <80mg/dL
   c. Repeat POC glucose checks and treatment q15 minutes until glucose is ≥80mg/dL.
2. Additional steps for BG <70mg/dL
   a. Draw STAT laboratory serum glucose measurement. Do not delay treatment with dextrose 50%.
   b. Screen the patient for hypoglycemia symptoms using Hypoglycemia Symptomatic Questionnaire.
      i. Repeat q15 minutes when glucose <70mg/dL

PROVIDER SIGNATURE	PRINT NAME	PAGER	NPI	DATE	TIME

PT.NO
NAME
DOB

UW Medicine
Harborview Medical Center – UW Medical Center
Northwest Hospital & Medical Center – University of Washington Physicians
Seattle, Washington

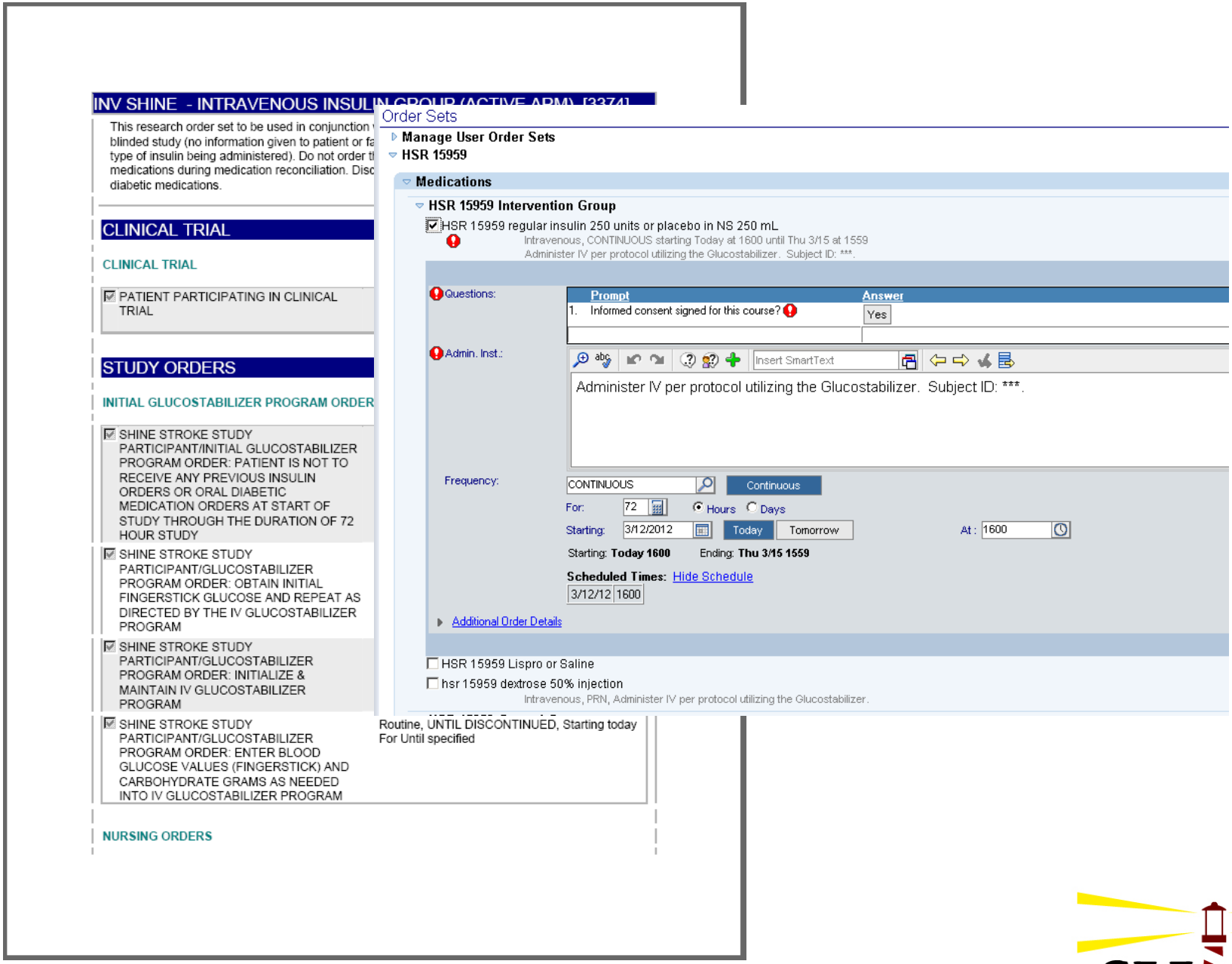
NEURO STROKE CONTROL GROUP ORDERS – SHINE
PAGE 1 OF 3

U3203
U3203

WHITE - MEDICAL RECORD

UH3203 REV NOV 12

SHINE


INV SHINE - INTRAVENOUS INSULIN GROUP (ACTIVE ARM) [3374]
This research order set to be used in conjunction
blinded study (no information given to patient or fa
type of insulin being administered). Do not order t
medications during medication reconciliation. Disc
diabetic medications.
CLINICAL TRIAL
CLINICAL TRIAL
PATIENT PARTICIPATING IN CLINICAL TRIAL
STUDY ORDERS
INITIAL GLUCOSTABILIZER PROGRAM ORDER
SHINE STROKE STUDY PARTICIPANT/INITIAL GLUCOSTABILIZER PROGRAM ORDER: PATIENT IS NOT TO RECEIVE ANY PREVIOUS INSULIN ORDERS OR ORAL DIABETIC MEDICATION ORDERS AT START OF STUDY THROUGH THE DURATION OF 72 HOUR STUDY
SHINE STROKE STUDY PARTICIPANT/GLUCOSTABILIZER PROGRAM ORDER: OBTAIN INITIAL FINGERSTICK GLUCOSE AND REPEAT AS DIRECTED BY THE IV GLUCOSTABILIZER PROGRAM
SHINE STROKE STUDY PARTICIPANT/GLUCOSTABILIZER PROGRAM ORDER: INITIALIZE & MAINTAIN IV GLUCOSTABILIZER PROGRAM
SHINE STROKE STUDY PARTICIPANT/GLUCOSTABILIZER PROGRAM ORDER: ENTER BLOOD GLUCOSE VALUES (FINGERSTICK) AND CARBOHYDRATE GRAMS AS NEEDED INTO IV GLUCOSTABILIZER PROGRAM
Routine, UNTIL DISCONTINUED, Starting today
For Until specified
NURSING ORDERS
Order Sets
Manage User Order Sets
HSR 15959
Medications
HSR 15959 Intervention Group
HSR 15959 regular insulin 250 units or placebo in NS 250 mL
Intravenous, CONTINUOUS starting Today at 1600 until Thu 3/15 at 1559
Administer IV per protocol utilizing the Glucostabilizer. Subject ID: ***.
Questions:
Prompt
Answer
1. Informed consent signed for this course?
Yes
Admin. Inst.:
Insert SmartText
Administer IV per protocol utilizing the Glucostabilizer. Subject ID: ***.
Frequency:
CONTINUOUS
Continuous
For:
72
Hours
Days
Starting:
3/12/2012
Today
Tomorrow
At :
1600
Starting: Today 1600
Ending: Thu 3/15 1559
Scheduled Times:
Hide Schedule
3/12/12 1600
Additional Order Details
HSR 15959 Lispro or Saline
hsr 15959 dextrose 50% injection
Intravenous, PRN, Administer IV per protocol utilizing the Glucostabilizer.

SHINE

Labels and Naming

Patient, Study A. **8STD-84XX**
XXXXXXXXXXX DOB: mm/dd/yyyy

insulin regular human/placebo **100units**
sodium chloride 0.9% **100mL**

Final Volume: **101mL**

Intravenous, Continuous, Rate: 0 - 5 ml/hr

Investigational Study Medication
HIC #2012-041 SHINE Trial
Adjust infusion as necessary based on finger stick glucose results.

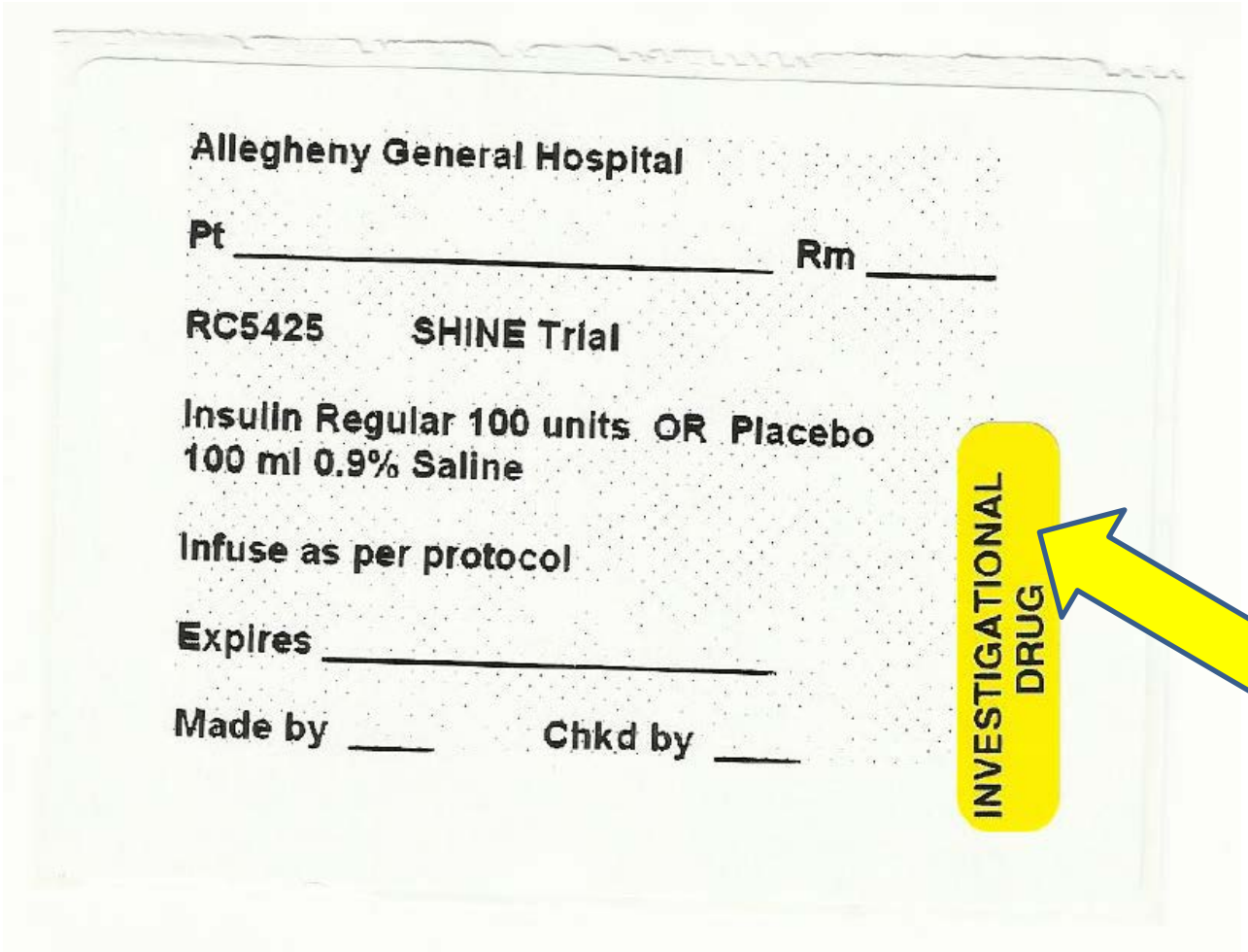
Due: 08/15/11 1500

Prepared At _____ _____ / _____
Stability: 24 Hours after prep time

Infusion label must not be unblinding

SHINE

Labels



Standard stickers can be applied (i.e. high risk or inv drug), but must include a matching 'PLACEBO' sticker required if 'INSULIN' sticker applied

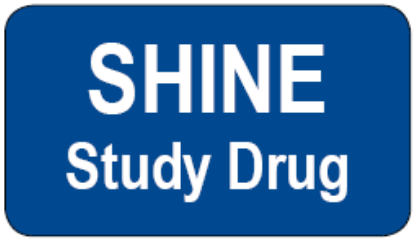
SHINE

Medical Record & Source Documentation

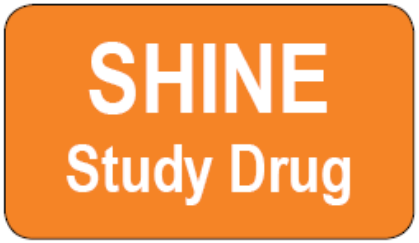
hsr 15959 insulin lispro 100 units/mL (HUMALOG) Freq: **3 TIMES DAILY WITH MEALS** Route: **Subcutaneous** Dispensed Volume: **3 mL** Administrations Remaining: **1** Order Start Time: **10/26/12 1730** Order End Time: **10/28/12 0400** Disp Location: **6 West Pyxis** Last Admin Given: **10/27/12 1723** **Admin Instruction:** For patients who are po or receiving bolus tube feeds. Administer SC per protocol utilizing the Glucostabilizer recommendations. Last 3 Actions: 10/27 0838; 10/27 1216; 10/27 1723 — Next 3 Scheduled:						
HSR 15959 regular insulin 250 units or placebo in NS 250 mL Freq: **CONTINUOUS** Route: **Intravenous** Dispensed Volume: **250 mL** Order Start Time: **10/26/12 1700** Order End Time: **10/28/12 0435** Disp Location: **UVA Inpatient Pharmacy** Last Admin Given: **10/28/12 0223** **Admin Instruction:** Subject ID: 5902. Administer IV per study protocol. When glucose > 500 mg/dL, notify house officer of glucose level. Mixture Administration Information Medication / Type / Amount	Rate/Dose Change 2257 MR 0.9 Units/hr 0.9 mL/hr		Rate/Dose Change 0007 MR 1.1 Units/hr 1.1 mL/hr [C]		Rate/Dose Change 0204 MR 0.6 Units/hr 0.6 mL/hr	Rate/Dose Change 0359 MR 0.7 Units/hr 0.7 mL/hr

SHINE Study Drug Stickers

- **Must** only be applied by pharmacist preparing study infusion



- Retain the sticker from one infusion bag for monitoring



- Study-supplied stickers for infusion (request resupply at least 2 wks in advance)

Anticipating Pharmacy Related Issues

- Required labeling due to high risk med
- Site-specific standard care preference for insulin pens/training for syringes
- Standard care protocols for dextrose-containing solutions

Study Laptops

SHINE

Preparing Study Laptops

- Review by IT or clinical engineering if needed
- Confirm preferred connection with IT and set as default
- Test laptops
- Consider storage location