



Study Orders

Center for Clinical Investigation

Subject Legal Name:

D.O.B.: Age:

Medical Record #:

Gender:

Ethnicity:

Race:

Admitting Information –

Date of Admit/Visit (Day 0):

Time of Admit/Visit:

Date of Discharge:

Time of Discharge:

Length of Stay (Number of Days):

Location of study: ☐ 9A

☐ 9B

Consent form:

☒ Subject has subject code

Visit Information:

VISIT 1 ☐ VISIT 2 ☐

Controlled Nutrient Diet YES ☐ NO ☐

Time Free Environment- YES ☐ NO ☐

Protocol Information

Protocol Title:

Principal Investigator:

IRB Protocol #:

IRB Expiration date:

Purpose

Medical Information

Diagnosis:

Allergies:

Subject-specific information

Subject handedness

Left ☐ Right ☐

Subject will receive an IV catheter:

YES ☐ NO ☐

Subject will receive a temperature sensor:

YES ☐ NO ☐

Subject will have urinary pregnancy test:

YES ☐ NO ☐

Dietary

Pharmacy

Inpatient Prescriptions

Medication Name; include dose, route, frequency, and duration of therapy (or number of doses).

If IV medication, include drug amount and volume (and concentration) with any special



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handling. Preparation instructions should be provided but not included with orders unless determined by pharmacy.

Study Day(s) _____

Study Date(s) ____/____/____

Time of administration ____:____ AM / PM

Time to have medication on floor ____:____ AM / PM

Discharge Prescriptions

Medication Name; include dose, route, frequency, and duration of therapy (or number of doses).

Study Day _____

Study Date ____/____/____

Date to have medication on floor ____/____/____

Time to have medication on floor ____:____ AM / PM

Equipment/Environment Required

Neurobehavioral Testing:

____ Yes ____ No

Lighting:

____, ___, lux

Environment Free of Time Cues:

____ Yes ____ No

Temperature Collection

____ Yes ____ No

Termiflex

____ Yes ____ No

Sleep Recording System

____ Vitaport 3 EEG Recorder: ____ Sleep and/or ____ Wake

____ Other: *(Name of other equipment)*

Study Specific Equipment: *(Name is Study Specific Equipment) - *See protocol for further instructions*

Nursing/Technician

STUDY SCHEMA: Total Study Length: One/two admission(s) each ____-days , separated by ____ weeks (day of admission is Day 1 (WP1). All days are ____-hour days, including ____ waking hours and ____ hours of scheduled bed rest

Admit Day 1: DATE (WP #1)

* [SEE DETAILED ADMISSION INSTRUCTIONS IN STUDY MANUAL] *

*** (DELETE FROM ORDERS if NOT using/performing those procedures.)

a) **All events are prescheduled in the automated scheduler (PRS).** Termiflex all events.

b) **Environment does/does not have to be maintained time free:**

c) **Free Time:**

- d) **Housekeeping** may enter the suite whenever convenient (i.e. subject is awake and not testing.) or may not...and specifics.
- e) *****The study-specific Bedtime and Waketime checklists must be completed** as you are carrying out the bedtime and waketime procedures each period (prompted by the PRS). **Sleep is not to be disturbed for any reason unless the subject signals for assistance.**
- f) **Light levels:** ____ lux during the WP#1 baseline day
- g) **Room temperature:** Should be set at ____°F for all days and not changed without paging the Project Leader.
- h) **Rectal temperature sensor:** *If subject to receive a temperature sensor (see above in “Equipment” section),* sensor to be worn continuously during the study after sensor instructions are given to subject per SOP on admission day. Have the subject check the probe position according to the SOP. [SEE TEMPERATURE RECORDING SECTION IN STUDY MANUAL].
- i) **Vitals signs:** All vitals per SOP or as follows... Vitals on admission and taken after all waketimes or
- j) **Medication: ***Study drug to arrive to unit no later than ____ pm each day.**
***~ RN to Termiflex “STUDY SPECIFIC EVENT” as subject swallows study drug pill.
 - a. *****Study Drug, ID-** _____/Placebo ____ mg, p.o., __ tablet(s) daily or ____ x ____ days, with ____ oz water, is to be given ____ min before/after scheduled waketime/bedtime as per PRS and may only be administered by a nurse.
 - b. Ferrous Gluconate (324 mg) p.o. ____ tablet(s) once/twice a day, *ONLY if blood samples will be collected.* Pills are to be given at breakfast/dinner and should be recorded in the medication log by the staff member who serves the meal
 - d. Other Medications must be ordered by MD (If Applicable) and may only be administered by a nurse.

[SEE DETAILED MEDICATION INSTRUCTIONS IN STUDY MANUAL]

- k) *****Neurobehavioral performance testing** will occur throughout the study at approximately ____-h intervals while awake, and more frequently close to awakening and/or bedtime. Testing consists of the ... (test names). Page Investigator for any problems with Neurobehavioral testing.

[SEE NEUROBEHAVIORAL TESTING IN STUDY MANUAL.]

- l). **IV insertion:** *If subject is to receive an IV,* it will be inserted on Day ____ (WP____) at time prompted by Protocol Reminder System and should not restrict arm movement (i.e., no antecubital or hand veins). Page PL if IV cannot be inserted.

Circadian Standard: IV catheter 20-18 g 1 ¼ inch with side ports in forearm with 12 ft tubing, manifold, and heparinized solution.

- **IV infusion (Standard/Non-Standard)**: 0.45% saline with _____ units heparin per liter infused at:
_____ cc per hour [_____ units heparin/hour] during study and Q_____ sampling periods

m) *****Biological Specimens:**

Urine: Send urine samples for urine toxicological and/or pregnancy tests per Lab Chart.

Urine Collections will begin on Day ____/WP #____ and is scheduled to be collected as prompted in the PRS for the remainder of the protocol.

Saliva Collections will begin on Day ____/WP #____ and is scheduled to be collected as prompted in the PRS for the remainder of the protocol.

Blood Collections will begin on Day ____/WP #____ and is scheduled to be collected as prompted in the PRS for the remainder of the protocol.

(SEE LAB CHART in orders for further information).

[SEE DETAILED SAMPLE COLLECTION SECTION IN STUDY MANUAL]

CCI Heparin-induced thrombocytopenia surveillance

1. SOP should be followed, per
Baseline Platelets _____
2. Has the subject received heparin in the past 100 days? YES ☒ NO ☐
3. If yes, date of first heparin initiation (D0) in the past 100 days: ###

Hemoglobin (Hgb): Must be performed per SOP at time of first blood sample (baseline value) and once per wake period as prompted per PRS when collecting blood samples via IV.

Study Day 2: (WP #2)

* All as ordered above except as noted below.

(ONLY INCLUDE CHANGES FROM FIRST DAY IN SUBSEQUENT DAYS BELOW)

- **Light levels:** ____ lux

- *****Biological Specimens:**

Urine/Saliva: Collection will begin on Day ____/WP #____ and is scheduled to be collected as prompted in the PRS for the remainder of the protocol. (SEE LAB CHART for further information).



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[SEE DETAILED URINE/SALIVA COLLECTION SECTION IN STUDY MANUAL]

- *****Polysomnographic (sleep) recordings** will be carried out on SP __ through SP __ per SOP.

[SEE DETAILED INSTRUCTIONS IN STUDY MANUAL]

Study Day __ : (WP # __)

* All as ordered above except as noted below.

(ONLY INCLUDE CHANGES FROM FIRST DAY IN SUBSEQUENT DAYS BELOW)

- **Light levels:** __ lux

- *****Constant Posture/Routine or Monitored Wakefulness (CP/CR/MW):** There will be a

__-hour CP/CR/MW period before/during SP/WP __ and SP/WP __ bedtimes per SOP.

[SEE CONTANT POSTURE/CR/MW INSTRUCTIONS IN STUDY MANUAL]

Discharge Day __ : DATE (WP # __)

* All as ordered above except as noted below.

- **Light levels:** __ lux

- *****Biological Specimens:**

Blood: Last blood sample __ hours after WT as prompted per PRS.

- *****D/C IV** following last blood sample. (Will prompt for RN to remove?)

- *****Medication:** Study Discharge prescription to arrive to unit by __am. PL to instruct subject on medications.

* [SEE DETAILED DISCHARGE INSTRUCTIONS IN STUDY MANUAL] *

LAB CHART (in order of draw)

☐ Urine HCG done on admission (Check if required)



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Time	Test	Tube	Volume	Special Instructions
ADMIT	Urine toxicology Urine pregnancy (if subject female)	Spec tube	30(mL)	Bring to SPA for Labcorp pick up/Send to LabControl
WP 1-__ :Urine				
Q__ Starting upon WP__	(Add tests to be run here)	__ mL tube (w/HCl)	10 mL	

WP __-__: Sal				
Q__ Starting WP__	Melatonin	Standard saliva tube	¾ full	

WP __-__: Blood				
Q__ Starting WP__	Melatonin	PTT	__ cc	
	Cortisol	GTT	__cc	

MD Signature: _____
Print Name: _____

Date: _____

PL Signature: _____
Print Name: xxx

Date: _____

Contact information

	Name	Pager/Cell Phone
Primary Medical Contact:		
Project Contact:		
Study Coordinator Contact(s):		