BRIGHAM AND WOMEN'S HOSPITAL
Center for Clinical Investigation
in partnership with Harvard Catalyst

Study Orders
Center for Clinical Investigation

Please indicate if this visit is an "INPATIENT" admission or an "OUTPATIENT" visit

Subject Legal Name:
D.O.B.: Age:
Medical Record #:

Gender:
Ethnicity:
Race:

Please delineate the different types of visits (specific to your study). This space is to identify if the visit is a screening visit, first or second visits, etc.
EXAMPLES:
Visit 1, Visit 2, etc
High Salt, Low Salt, etc

Admitting Information "INPATIENT" or "OUTPATIENT"

Date of Admit/Visit (Day 0):
Time of Admit/Visit:
Date of Discharge:
Time of Discharge:

Visit Information:
Length of Stay (Number of Days):
Location of study:
Consent forms:

Please indicate where the study will take place: (9A, 9B, ACC, CTC, other)

Here, please indicate if there are outstanding paperwork or items important to address before conducting study. Consent forms were "Signed before arrival" *or* "Need to be sign upon arrival"*Other options:*
- Signed consent for genetic testing
- Signed consent for extra blood and/or urine to be stored for future use

Protocol Information

Protocol Title:
Principal Investigator:
IRB Protocol Number:
IRB Expiration date:

Purpose

To determine efficacy of. . . .

Please give a brief summary of the purpose of this study. (2 sentences max.)

Medical Information

Diagnosis:
Allergies:

Please disclose any medical information that is participant specific and pertinent to the study. For example, the participant may be diabetic or have a latex allergy.
**Make sure to input home medications in PAML*

Dietary

Dietary orders are written to be specific in designing the subject's diet and for providing those foods consistent with the protocol needs. They may be as simple as a therapeutic diet or any variation of a research diet requiring controlling nutrient intake for macro/micronutrients or specific foods. Examples:

Inpatient Protocols (subject stays in overnight for 1 day or more)

1. **Study Visit**: Identify study visit number if this is a continuation protocol requiring a research diet or dietary modification.
Ex. □ Study Visit 1 □ Study Visit 2 □ Study Visit 3

2. **Diet Order**: Define Diet order: (there may be more than one if the subject changes from one diet to another: i.e. high salt to low salt, etc)
Non research diet
Ex. *House diet*, *ADA diet* (diabetic), *NAS* (no added salt)
Research diet. Include as applicable:
▪ Type of diet (be specific)

Ex. *Controlled nutrient diet* – intake of macronutrients and/or micronutrients are controlled and the same daily. Typically a subject must finish all food in order to maintain a controlled amount or distribution of nutrients.

- *Isocaloric* – calories are adjusted to individual to maintain weight
- Macro and/or micronutrients to be controlled (include % variation)

  Macronutrients:

  Ex. *55% carbohydrate (+/-5%), 20 % Protein (+/-5%), 25% Fat (+/-5%)*

  Micronutrients: Sodium and potassium are frequently calculated +/- 2 mEq for studies with tight control or +/- 20% for studies requiring a broader range of intake, but still maintaining some control. Calcium: frequently calculated +/- 50 mg

  Ex. *10 mEq Na (+/- 2 mEq), 100 mEq Na (+/- 20%)*

  Ex: *1000 mg Ca (+/- 50 mg)*
- Water:

  Ex: *Water ad lib, 2.5 liters, etc, 2.0 liters minimum.*
- MUST FINISH: subjects must finish all food in order for their intake to meet their calorie requirements and/or the nutrient targets as defined.
- Other dietary components:

  Ex ; *No caffeine, decaffeinated or herbal beverages, chocolate*

  No grapefruit juice

3. **Admission protocol Instructions**
   - Admit Day 0 (same as for all other instructions)
   - Date
   - Study Day number in parentheses: this is applicable for studies where a participant has been on an outpatient diet prior to study testing.
   - Indicate if study diet is a continuation of an outpatient diet

     Ex. *Continue low salt diet*
   - First meal to be served to subject upon admission. If options are available to subject may use box format.

     Ex: □ *Admit to 9A for Dinner & snack*

     □ *Admit to 9A for snack*

4. **Additional days** – nothing necessary unless diet or feeding is being changed in some way.

5. **Discharge Day, date study day** : Admit day ….. State if diet is being changed or continued as an outpatient.

Ex, Admit Day 5, 12/18/08 (Study Day 8) : *Ad lib or study breakfast (or lunch) following study completion Discharge subject with LS (low salt) study meals.*

<u>Outpatient single day study on 9A/B/ACC/CTC (subject is on unit for part of a day and does not stay overnight)</u>

1. Outpatient single day study <u>not</u> on continuation study diet.

- **Admission 2-3 hrs fasting:**

Standard snack (fruit juice, canned fruit cup, cereal bar): Given to fasting subjects after a testing procedure of 2-3 hrs.

▪ **Admission 4-5 hrs**:
Box lunch (turkey sandwich, chips, fresh apple, 1% milk): Given to subjects after a 3-5 hr outpatient admission. Not available until after 11 AM.

▪ **Full day admission:**
Meals dependent on study duration.
Ex. Provide lunch and dinner. D/C 7 PM.

2. Outpatient single day study on continuation study diet (9A/B/ACC/CTC).

1. **Study Visit**: Identify study visit number.
Ex. □ *Study Visit 1* □ *Study Visit 2* □ *Study Visit 3*

2. **Diet Order**: Follow instructions as in Inpatient Diet Orders

3. **Protocol Instructions**
▪ Admit Day 0 (same as for all other instructions)
▪ Identify first meal to be served to subject upon admission.
Ex. If a new phase of the diet: *Begin low salt diet with breakfast, following testing.*
Ex. If continuing a study diet: *Continue low salt diet with breakfast following testing.*
▪ Discharge instructions:
Ex. *Discharge subject with LS (low salt) study meals.*
Ex. *Serve subject study lunch and d/c with study meals*

Outpatient Diet Orders for subjects following a diet prior to testing or subject admission. Faxed to Dietary Office (617-732-7900) 2 weeks prior to feeding. Use same Protocol Template and include the following:

▪ Diet Order: Follow same guidelines as number 1 above.
▪ Diet start date.
▪ Admit date and meal for testing if applicable. Dietary will arrange food pick up dates with subject.
▪ Subject specific information should be included for calculating controlled nutrient diet prior to testing or any nutrition related issue which requires the dietitian to contact the subject prior to admission.
i.e. height, weight, age, gender
telephone contact numbers (W), (H), (C)
Which telephone number is best to use for contact?
E-mail address; Do you read email regularly? □ Yes □ No
▪ Division of Sleep Medicine: Provide "Food meal schedule identifying date, wake period, time in military time, meals – B,L,D,Sn) and completed Food Preference Sheet.

Assistance: Janis Swain, MS, RD
Contact: (jswain@partners.org) 617-783-7783
Bionutrition Manager, Metabolic Phenotyping Core, CCI

Study Orders
Center for Clinical Investigation

Pharmacy

Pharmacy Section Training

For assistance or to initiate a new trial that involves medication, please contact the Investigational Drug Services Pharmacy at x26410 or email BWHRXIDS@partners.org.

Front Page

In addition to the usual subject admitting information obtained from the cover sheet, the cover sheet will provide subject randomization and study information that the pharmacy will utilize for enrolling, randomizing, assigning treatment, blinding, preparing, and documenting medication and treatment for a subject.

Pharmacy Section

All medication orders will be written into BICS. Please contact IDS to have the medications for the trial be entered into BICS. The paper orders will contain a copy of these orders such that other clinical staff will be able to review all the orders within a single template.
Within the pharmacy section of the paper orders, all physician orders will be written as required by law. Both inpatient and outpatient orders will be indicated on the paper order sets and these must be clearly defined by a sub-header within the section. Please note that inpatient orders must be written in BICS. Orders written in BICS are those that will be utilized by pharmacy as the actual orders. Change orders will also be written in BICS.

The format used will follow the same format as seen for orders written in CPOE via BICS. Outpatient orders will be written onto outpatient prescriptions. Pharmacy will provide standardized prescription templates to use. The content of these prescriptions must be approved by one of the investigators. On the standardized template, this named "Discharge Prescription."

Each order must indicate the following for each drug:

- Medication name (list both generic and brand name, if available)
- Dose
- Route
- Frequency
- Duration of therapy

Other required information includes study day, date, and time for administration time or drug availability on the unit.

On the standardized template, you will see the following information for your use as a guide.

Pharmacy
Inpatient
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 handling. Preparation instructions should be provided but not included with orders unless determined by pharmacy.
Study Day(s) ____
Date(s) _____/_____/_____
Time of administration _____:_____ AM / PM

Study Orders

Center for Clinical Investigation

Time/Date to have medication on floor: _____:_____ AM / PM
Discharge Prescription
Medication Name; include dose, route, frequency, and duration of therapy (or number of doses).
Study Day ____
Study Date _____/_____/_____
Time/Date to have medication on floor: _____:_____ AM / PM

Please follow the examples below as a guide for how to write specific orders. Note that instructions may be included with any of the orders.

Please follow the examples below as a guide for how to write specific orders. Note that instructions may be included with any of the orders.

1. Oral medication (no end date)

ID-Atenolol 50 mg PO QD

If protocol defines days as "study day", indicate the "study day(s)" the medication will be administered. If "study day" is not used, fill in N/A.

Medication Order

Pharmacy
Inpatient

1. ID-Atenolol 50 mg PO QD

Study Day(s)
Date(s) 10/25/08 – 10/28/08
Time of administration 08:00 PM
Time/Date to have medication on floor: 3:30 PM starting 11

Indicate the date(s) the medication will be administered.

Indicate the time(s) medication is to be given.

Specify date(s) and time(s) medication should be delivered. NOTE: Deliveries are made at 8:00 am and 3:30 pm

2. Oral medication (with specified end date or number of doses)

ID-Atenolol 50 mg PO QD x5 doses, start 11/25/08 @ 8am

Pharmacy
Inpatient
Study Day(s)
Date(s): 11/25, 11/26, 11/27, 11/28, & 11/29
Time of administration 08:00 AM
Time/Date to have medication on floor: 3:30 PM starting 11/24/08

1. ID-Atenolol 50 mg PO QD x5 doses

3. Oral medication with dose range

ID-**Acetaminophen 500-1000 mg po QID prn**

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08 – 11/15/08
Time of administration 08:00 PM
Time/Date to have medication on floor: Floor stock to be used

1. ID-Acetaminophen 500-1000 mg po QID prn
- Floor Stock to be used

4. Oral medication involving titration

ID-Prednisone 40 mg PO Q12H x 4 doses, 30 mg PO Q12H x 4 doses, 20 mg PO q12h x 4 doses, 10 mg PO Q12H x 4 doses, 5 mg PO Q12h x 4 doses, then 5 mg PO QD

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08 – 10/28/08
Time of administration 08:00 AM & 08:00 PM
Time/Date to have medication on floor: 07:30 AM and 3:30 PM starting10/25/08

1. *10/25/08, 10/26/08*
ID-Prednisone 40 mg PO Q12H x 4 doses

2. *10/27/08, 10/28/08*
ID-Prednisone 30 mg PO Q12H x 4 doses

3. *10/29/08, 10/30/08*
ID-Prednisone 20 mg PO Q12H x 4 doses

4. *10/31/08, 11/01/08*
ID-Prednisone 10 mg PO Q12H x 4 doses

5. *11/02/08, 11/03/08*
ID-Prednisone 5 mg PO Q12H x 4 doses

6. *11/04/08 onward*
ID-Prednisone 5 mg PO QD

5. Oral medication with dosing that requires blinding

ID-Melatonin 2.5 mg / 0 mg PO QHS

Pharmacy
Inpatient
Study Day(s)
Date(s): 11/25, 11/26 & 11/27
Time of administration: 30 minutes prior to bedtime
Time/Date to have medication on floor: 03:30 PM beginning 11/25/08

1. ID-Melatonin or Placebo 2.5 mg/ 0 mg PO QHS x 3 doses

6. IV push

ID-Ondansetron 2 mg IV push over 2 mintues Q6H x 2 doses

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08 – 10/26/08
Time of administration: post-op
Time/Date to have medication on floor: by 07:30 AM on 10/25/08

7. IV Bolus

ID-PAH 8 mg/kg IV Bolus x1

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08
Time of administration: 07:00 AM
Time/Date to have medication on floor: by 03:30 PM on 10/24/08

1. **ID-PAH 8 mg/kg IV Bolus x1**
   - Dispense 1x20 ml (250 mg) vial of PAH

8. IV Bolus followed IV continuous infusion

ID-Furosemide in NS; Bolus 80 mg followed by 10 mg/hr

- **Instructions: IV Continuous Infusion for 5 days (120 hours)**

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08 – 10/30/08
Time of administration: 07:00 PM
Time/Date to have medication on floor: by 3:30 PM on 10/25/08

1. **ID-Furosemide in NS (2 mg/ml); 80 mg IV Bolus**
2. **ID-Furosemide in NS (2 mg/ml) IVCI 10 mg/hr over 5 days (120 hours); start immediately after IV Bolus**

9. IV medication with dose range

ID-Hydromorphone in NS 0.1-0.2 mg/kg/hr IVCI

- Instructions: Begin at 0.1 mg/kg/hr, increase to 0.2 mg/kg/hr if pain persists. Discontinue when patient can tolerate oral medication.

Pharmacy
Inpatient
Study Day(s)
Date(s):) 10/25/08 – 10/30/08
Time of administration: post-op
Time/Date to have medication on floor: by 3:30 PM beginning 10/25/08

1. **ID-Hydromorphone in NS (100 mg/50 ml) 0.1 to 0.2 mg/kg hr IVCI**
   - Initial rate = 0.1 mg/kg/hr. May increase to 0.2 mg/kg/hr if pain

10. IV medication involving admixture (i.e. PAH/Inutest)

ID-PAH/Inustest (7.2 g/18 g in NS qs to 220 ml) IVCI at 22 ml/hr

- Run infusion until t=300

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08
Time of administration: 07:00 AM
Time/Date to have medication on floor: by 03:30 PM on 10/24/08

1. **ID-PAH/Inutest Infusion 7.2 g/18 g in NS qs to 220 ml, IVCI @ 22 ml/hr until t=300**

PAH (1 gram/5 ml)	7.2 grams (36 ml)
Inutest (5 grams/20 ml)	18 grams (72 ml)
Sodium Chloride 0.9%	112 ml
Total Volume =	220 ml

11. IV/Oral medication with doses that differ on different days

NOTE: If different doses exist, then multiple orders must be entered.

- ID-PAH 8 mg/kg IV Bolus x1 on 10/25/08 and 10/26/08
- ID-PAH Infusion 3 grams IV in NS qs to 105 ml on 10/25/08
- ID-PAH Infusion 6 grams IV in NS qs to 210 ml on 10/26/08

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08 & 10/26/08
Time of administration: 07:00 AM
Time/Date to have medication on floor: 03:30 PM on the 10/24/08 and 10/25/08.

1. **ID-PAH (2 grams / 10 ml) 8 mg/kg IV Bolus x1**
   - Dispense 1 vial x 20 ml vial

2. **ID-PAH Infusion 3 grams IV in NS qs to 105 ml**

PAH (1 gram/5 ml)	3 grams (15 ml)
Sodium Chloride 0.9%	90 ml
Total Volume =	105 ml

3. **ID-PAH Infusion 6 grams IV in NS qs to 210 ml**

PAH (1 gram/5 ml)	6 grams (30 ml)
Sodium Chloride 0.9%	180 ml
Total Volume =	210 ml

Study Orders

Center for Clinical Investigation

12. Inpatient Dispense and Discharge prescription
    - **ID-Ferrous Gluconate 325 mg PO BID x10 doses**
    - **ID-Ferrous Gluconate 325 mg PO BID x21 days, dispense #42 on 11/25/08**

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08 – 10/31/08
Time of administration: 07:00 AM and 07:00 PM
Time/Date to have medication on floor: by 03:30 PM beginning 10/25/08.

1. **Ferrous Gluconate 325 mg PO BID x10 doses**
   - Dispense 10 x 325 mg tablets

Discharge Prescription

Date to have medication on floor 10/29/08
Time to have medication on floor 08:00 AM

2. **Ferrous Gluconate 325 mg PO BID x 21 days**
   - Dispense 42 x 325 mg tablets (pursuant to outpatient prescription)

13. Example of listing for more than one medication
    - ✓ ID-Captopril 25 mg PO QD
    - ✓ ID-Ferrous Gluconate 325 mg PO BID x10 doses
    - ✓ ID-Melatonin 2.5 mg/0 mg PO QD
    - ✓ ID-Ferrous Sulfate 325 mg PO BID x21 days (discharge script)

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08 through 10/28/08
Time of administration: 07:00 AM
Time/Date to have medication on floor: 3.30 P

1. **ID-Captopril 25 mg PO QD**
2. **ID-Melatonin 2.5 mg/ 0 mg PO QD**

When multiple medications have the same administration time and delivery schedule, those medications can be listed together followed by administration information.

Study Day(s)
Date(s): 10/25/08 through 10/28/08
Time of administration: 07:00 AM and 07:00 PM
Time/Date to have medication on floor: 03:30 PM and 7:30 AM starting 10/25/08 (PM dose)

3. **Ferrous Gluconate 325 mg PO BID x10 doses**

Discharge Prescription
Date to have medication on floor 10/29/08
Time to have medication on floor 08:00 AM

4. **Ferrous Gluconate 325 mg PO BID x 21 days**
   - Dispense 42 x 325 mg tablets (pursuant to outpatient prescription)

14. IV continuous infusion

ID-Drotrecogin 20 mg/100 ml in NS @ 24 mcg/kg/hr x 96 hours
Instructions: Infuse via a dedicated IV line

Pharmacy
Inpatient
Study Day(s)
Date(s): 10/25/08 through 10/10/31/08
Time of administration: 02:00 PM
Time/Date to have medication on floor: by 12:00 PM beginning 10/25/08

1. **ID-Drotrecogin 20 mg/100 ml in NS @ 24 mcg/kg/hr x96 hours**
   - Infuse via a dedicated IV line

Nursing/Technician

Please write orders to include daily activities and interventions that are necessary for each day of the participant's stay. This should include all events such as weights, heights, ECG recordings, O2 sat, vital signs, special BP's.

Each day should be listed chronologically with the day of admission being day 0. Please list all activities chronologically within its specified day.

Specific details addressed in other sections should not be repeated but the directives for nursing need to be included in the daily orders. For example the order for the RN to administer study medications needs to be included in this section with drug name, dose route and time (but not the same preparation instructions as in IDS pharmacy section.)

Other Examples:
Dietary: DO NOT repeat "patient is on a 10 meq Na/100meqK 2500 mL minimum diet" as this is specified in the dietary section. BUT include: the direction for when the patient may/should eat.

Lab: DO NOT repeat information regarding sample size, tube color, handling etc. BUT include: information which the nurse may need to properly collect the samples, such as "do not use tourniquet" or "do not use heat pack," etc.; priority of sample draw in case of IV issues.
(Please use "**Refer to Lab Chart**" in bold)

IDS Pharmacy: DO NOT repeat the concentration calculations, BUT include: information the nurse needs to administer the medication, drug, route, time, and frequency: "Start infusion 2 hours after wake time"

Study Orders

Center for Clinical Investigation

MEDICATIONS: MD must have clinical privileges and Order Entry authorization. (See departmental administrator if key does not function for Order Entry.) All personal medications allowed/required during study need to be entered by MD in PAML and in BICS Order Entry. Please specify in Order Entry "may self administer own medication" for each medication this applies.

SAMPLE
Day 0: _____(Admit Day)
Special needs summarized
Please summarize any additional instructions for example:

- "May go off unit but not out of hospital following study infusion."
- "Use metric system for all measurements"
- "Use military time to document all events"
- "Use study EKG machine for all recordings"
- "Use study automated BP device for all vital signs"
-

1. Admit to Dr Study Investigator
2. Admission blood work and urine tests (refer to lab chart)
3. Begin 24hr urine collection
4. Weigh subject in hospital gown
5. Check vital signs (HR,BP,RR, Temp) in chair after 15minutes of resting
6. Timing of any meals and/or snacks if timing is critical

Include baseline/admission data to be collected as well as the instructions for continuing any urine collections, for Vital signs, weights, etc,
Include instructions if lab results are out of normal range.
Indicate if subject is to be NPO or allowed water and supine at specific bedtime, and if allowed out of bed during evening/night before next day study.
Write instructions for any equipment or supplies required to be ready for early AM study next day.

Day 1: _____
Indicate all data collections (BPs, HR,RR, Temp) prior to any study interventions
Order IVs for infusions and /or blood draws
(Example" Insert 2 IVs 1/2NS at 20ml on pump. One IVin each arm, Left arm for infusion and Right one for blood draws".)
State timing for start of blood draws per lab chart
(Labs will be written as "refer to lab chart" (bold).)
Indicate when MD to be called or any parameters that may change study timing.
Indicate meal times during/ after study interventions
State if subject is free to go out on pass per BWH policy after interventions completed.

Day 2: _____
Address the same items as Day 1 and additional instructions for Discharge

(Labs will be written as "refer to lab chart" (bold).)

LAB CHART

BRIGHAM AND WOMEN'S HOSPITAL
Center for Clinical Investigation

Study Orders

Center for Clinical Investigation

Complete the chart in the order of draw and separated by day. Include all biological specimen collections (blood, urine, saliva, etc.)

Please do not include specific processing instructions. These will be kept on file in the SPCL.

Please indicate if subject should have HCG-STAT upon admission as first item.

Time	Test	Tube	Volume (mL)	Special Instructions Or Comments
Day 0:				
				Example: Sample to be kept on ice
				Tube cannot be opened
Day 1:				

***In order to add more rows, highlight a row near which you would like to add another row, go to the "Table" tab on the top bar, go down to "Insert" → "row" and chose either above or below.*

MD Signature: _____ Date: _____
Print Name: _____

Primary Contact information

	NAME	EXTENSION	PAGER or Cell phone
Primary Contact:			
Secondary Contact:			
Study Coordinator Contact(s):			

Primary contacts should be the MD or NP available for medical questions/concerns.