

## **GUIDELINES AND INFORMATION REQUIRED FOR LONG OUTPATIENT VISITS**

*Long outpatient visits protocols are often the most complex. Collaboration between investigators, study coordinators, nursing staff, and the subjects is absolutely essential to their successful completion. Please adhere to these guidelines to maximize the potential for a productive and collegial research project. Note that these guidelines are temporary and we are working hard to move this entire process to the Web. To download the long outpatient pre-admission forms packet, click [here](#).*

### **A. Prior to Protocol Review at the Irving Institute Clinical Advisory Committee (ClinAC)**

1. Meet with Ms. Jennifer Shepp (Patient Care Director), to discuss the Harkness 10 nursing, specialized equipment, storage, or other resources that you will need, as well as the duration of the study and the number of projected admissions. This is especially important if this is an industry-sponsored protocol since budgeting changes via the Clinical Trials Office may be required to meet the protocol needs.
2. Complete an example of the flow sheet for your study available on page 3 of the [pre-admission forms packet](#), delineating what is expected from the nursing staff and when it needs to be done. Also please indicate duties that are performed by members of your research staff and the order in which they are performed, e.g., if subjects need an EKG by the coordinator and vital signs by the nurse, which one is done first? This type of early detailed description leads to a much smoother study and also alerts nursing to any staffing or other issues in advance. Also, please list any special set up requirements and possible side-effects of drugs administered. This sheet will be a quick and valuable resource and will hopefully avoid repeated telephone calls or emails for protocol clarification.

### **B. Prior to Scheduling Any Admissions:**

1. After approval by ClinAC, the investigator and research coordinator(s) must meet on Harkness 10 with nursing staff to review the protocol, and what specific tasks are involved. Research orders for most protocols cannot currently be entered into Eclipsys. In order to make sure that the research orders are clear, the investigator must submit a sample of the admitting orders to the Patient Care Director (Jennifer Shepp or her designee) for approval and respond to any inquiries regarding order clarity. A sample of what is required can be found on Page 4.

### **C. Scheduling Admissions:**

**To avoid scheduling conflicts, please schedule these admissions at least 1-2 weeks in advance. We are also happy to schedule multiple visits for an individual up to 3 months in advance.**

1. To request an admission to Harkness 10 for a long outpatient visit, please complete the [pre-admission forms packet](#) and email it to [LOPforms@columbia.edu](mailto:LOPforms@columbia.edu). The forms packet includes:
  - a) Statement requesting the date and time of admission as well as the subject (name and CRR#), the protocol (name and ClinAC#), investigator and coordinator (name and contact info), notification if this is the first time this protocol is being run and whether or not more than 3 blood samples are required.
  - b) Long outpatient subject admission sheet.
  - c) Flow sheet that should include the specific times at which research events are expected to occur and who performs them.

**Please note that your subject has not been registered as an admission until you have received a confirmation email from Ms. Elizabeth Guerrido, Ms. Dione (D) Brown, or Mr. Ismael Castaneda.**

2. A copy of a signed active (not expired) consent form must be delivered or faxed (**212-342-5310**) to a Unit Assistant on Harkness 10 for all new admissions. For studies with multiple admissions, the unit will keep a copy of the consent on file. If the study has been renewed since the original consent form was signed, please make sure that the Harkness 10 staff has a copy of the IRB approval letter allowing your study to continue unchanged.

3. Orders: The hospital computer system is not available for research orders. Please bring the signed research orders to Harkness 10 and give them to the Unit Assistant no later than 6PM the night before your admission. It is acceptable to fax these orders (212-342-5310) but note that your study cannot begin on the admission date until a set of orders with the original signature has been given to the Unit Assistant.
  - a) If this is a small study (10-20 subjects) the orders must be hand-written for each participant. Order sheets can be obtained from the Harkness 10 staff.
  - b) If this is a study that will have more than 20 subjects, orders must be presented to the NYP Forms Committee (Diane Muscente at 212-746-0515) which meets at 2:00PM on the 2<sup>nd</sup> Wednesday of each month. Requests for forms should be submitted at least 2 weeks in advance. Once approved, you can order a pad of pre-printed orders. Instructions for ordering forms are available from the Forms Committee.
  - c) For each admission please bring any specimen tubes or other equipment to be used during the study to the unit (HP10) on the day of admission. Please hand the tube set ups/equipment to the nurse assigned to your study (the Unit Assistant or the Charge Nurse can identify that person). Note that all equipment must be approved by the Biomedical Service (212-305-6321) in advance.
  - d) **Please note that if booking is not completed in advance, if you have not received a confirmation email, if a signed consent form is not on file, or if the original signed orders are not present, the nurses will not be able to initiate the study and your long outpatient stay may be declined.**

#### **D. During Admission**

1. Harkness 10 cannot provide meals for subjects enrolled in long outpatient visits. Please make arrangements with your subjects to bring their own brown bag lunch or you may order something from an outside vendor providing that someone is designated to go to the lobby to pick up the order. Harkness 10 can only provide coffee, tea, or ice water.
2. Please make sure the Research Pharmacy is aware of any time constraints regarding study medications. If study medications are not provided, the nurse will contact the study investigator or research coordinator who will then contact the Research Pharmacy.
3. For studies that are high risk or for which serious adverse events have been reported in the literature, the Principal Investigator/ MD designee is expected to be on the unit during the period of high risk.
4. In scheduling your patients and/or nursing procedures please keep in mind that the nurses round from 8-8:45AM and from 4-4:45PM. Rounding is essential to the transfer of patient care between shifts and nursing availability for research protocols is reduced at these times.
5. Harkness 10 cannot provide medications beyond acetaminophen. If anti-emetics, diphenhydramine, or other medications may be required, please provide them on the day of admission. If subjects will be taking their own medications during the stay, please put these medications in the orders (including dose, frequency, and time of administration) and tell the subjects that these medications will have to be certified by the pharmacy.
6. If study personnel are designated to pick up patients, or process and deliver specimens, please make sure that this is done in a timely manner.
7. Finally, just a reminder that completion of these studies depends upon collegial collaboration of investigators, research coordinators, nurses, and subjects. Please do not discuss any personal matters or other patients, or address any issues regarding protocols (missing data, feelings about investigators, etc.), in front of subjects. If any issues arise, please discuss them in a discrete location.

**Booking subjects well in advance, providing relevant paperwork, and clear delineating of responsibilities will optimize the capability of assuring adequate staffing and successful study completion.**

**Summary of Relevant Contact Information:**

Ms. Jennifer Shepp (Patient Care Director, [jrs9026@nyp.org](mailto:jrs9026@nyp.org)): 212-305-6632

Ms. Melvina Williams (Unit Assistant, [daniema@nyp.org](mailto:daniema@nyp.org)): 212-305-6632

Mr. German Ferreiras (Unit Assistant, [gef9002@nyp.org](mailto:gef9002@nyp.org)): 212-305-6632

Harkness 10 Fax: 212-342-5310

Forms Committee: 212-746-0515

Biomedics Service: 212-305-6321

Research Pharmacy: 212-305-6888

**Checklist:**

- Meeting with Ms. Jennifer Shepp and completion of flow sheet prior to study submission to ClinAC
- Meeting with nurses and submission of sample research order set once ClinAC approval obtained
- Admission request email to [LOPforms@columbia.edu](mailto:LOPforms@columbia.edu)
- Email confirmation reply received
- Long outpatient subject admission sheet and flow sheet
- Signed active consent for subject available
- Order set for each admission with original signature
- Research pharmacy aware if applicable
- Meals and any patient medications are arranged for

**CITE THE GRANT** - Publications resulting from Irving Institute support should reference Columbia's CTSA grant. By accepting Irving Institute support you agree to include the following citation in your publications:

**“This publication was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant Number UL1 TR001873. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.”**

**NewYork-Presbyterian**  
The University Hospital of Columbia and Cornell



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**DOCTOR'S ORDERS**

**SAMPLE  
ORDERS**

IF APPLICABLE, PRINT NAME, SEX AND MEDICAL RECORD NO.

AUTOMATIC STOP ORDER POLICY	RE-ORDER TIME	AUTOMATIC STOP ORDER POLICY	RE-ORDER TIME
Large volume parenterals/IV's	24 hours	IV Vancomycin	96 hours
Controlled substances (schedule II-V)	7 days	IV H2-Receptor Antagonists (ie. Famotidine)	5 days
IV antibiotics	7 days	Warfarin	q24hx7d, then 7 days
Oral antibiotics	14 days	Maintenance medications	30 days

**LEGIBILITY and COMPLETENESS of medication orders counts - Please follow these Guidelines:**

- Write out "units"
- Use leading zero, eg. 0.1 mg
- Write out "days" or "doses"
- Write out "microgram"
- Omit trailing zero, eg. 1 mg
- Print medication order
- Print name and ID code
- Sign all orders
- Add beeper number

DATE/TIME	DOCTOR'S ORDERS	AND	DOCTOR'S SIGNATURE	ORDER POSTED BY WHOM DATE, TIME	ORDER CHECKED BY RN DATE, TIME	ORDER FAXED DATE, TIME
	*ALLERGIC/SENSITIVE TO:					
	Date & Time					
	Admit patient to ICCR (HP10) on _____ study, ICCR #, IRB #					
	Condition:					
	Allergies:					
	Diet:					
	Vital signs:					
	Height and weight:					
	Activity:					
	Study Medication (and administration guidelines):					
	Other Medications (includes analgesics, sedatives, laxatives and home meds)					
	Study specifics:					
	Specimen acquisition: (times to be obtained)					
	Conditions for processing specimens (incl. RPMs, duration and temp for centrifuging)					
	Example: Collect 1 lavender top tube at each timepoint					
	Centrifuge at 2300 RPMs at 4C for 20 minutes					
	Separate plasma/serum into transfer tubes (provided by investigator)					
	Refrigerate or freeze (-20 or -80 freezer)					
	Specimens will be picked up by study coordinator					
	Contact personnel:					
	Primary investigator: _____ (beeper & extension)					
	Admitting MD: _____ (beeper & extension)					
	Study Coordinator: _____ (beeper & extension)					
	In an emergency, call _____ (beeper & extension)					
	Legible signature of MD _____					

(\*) Required only for admissions, transfers where Graduate Staff coverage changes, and when new allergies are identified.