GUIDELINES AND INFORMATION REQUIRED FOR LONG OUTPATIENT VISITS

Long outpatient (LOP) 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 by the Irving Institute Clinical Advisory Committee (ClinAC)

1. Meet with Patient Care Director, Ms. Ariella Kelin, to discuss the Harkness 10 nursing, specialized equipment, storage and 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. 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.

B. Prior to Scheduling Any Admissions:

1. After approval by the CRR Advisory Committee (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. The investigator must submit a sample of the admitting orders to the Patient Care Director (Ariella Kelin 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 2 weeks in advance. We are also happy to schedule multiple visits for an individual up to 3 months in advance.

To request an admission to Harkness 10 for a long outpatient visit, please call the unit, 212-305-6632, and confirm appointment availability. Once availability has been confirmed complete the pre-admission forms packet and email it to LOPforms@columbia.edu. **Please note that your participant has not been registered as an admission until you have received a confirmation email from Ms. Ariella Kelin or her designee.** Please allow up to 48 hours to receive confirmation.

1. The Long Outpatient (LOP) Request Form includes:
   a) LOP participant admission sheet
   b) Nursing Flow Sheet
2. A PDF file of a signed, active **(not expired)** consent form must be emailed to Ariella Kelin ark9040@nyp.org 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 be sure to email Ariella Kelin a copy of the IRB approval letter allowing your study to continue unchanged.
3. **Orders**:
   a) All study team members are required to attend an Epic training session.
   b) All orders must be placed in Epic as signed and held at least 72 hours prior to the visit, to allow enough time for review.

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 your 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. <u>During Admission</u>

1. Harkness 10 cannot provide meals for participants enrolled in long outpatient visits. Please make arrangements with your participants 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. If study personnel are designated to pick up participants, or process and deliver specimens, please make sure that this is done in a timely manner.
5. Finally, just a reminder that completion of these studies depends upon collegial collaboration of investigators, research coordinators, nurses, and participants. Please do not discuss any personal matters or other participants, or address any issues regarding protocols (missing data, feelings about investigators, etc.), in front of participants. If any issues arise, please discuss them in a discrete location.

Booking participants 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. Ariella Kelin (Patient Care Director, ark9040@nyp.org): 212-305-6633

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

Ms. Donnis Haynes (Unit Assistant, doh9057@nyp.org): 212-305-6632

Harkness 10 Fax: 212-342-5310

Forms Committee: 212-746-0515

Biomedical Service: 212-305-6321

Research Pharmacy: 212-305-6888

Checklist:

- ☐ Meeting with Ms. Ariella Kelin and completion of flow sheet **prior to** study submission to CRR
- ☐ Meeting with nurses and submission of sample research order set once CRR approval obtained
- ☐ Admission request email to LOPforms@columbia.edu
- ☐ Email confirmation reply received
- ☐ Long outpatient participant admission sheet and flow sheet
- ☐ Signed active consent for participant available
- ☐ Order set for each admission with original signature
- ☐ Research pharmacy aware, if applicable
- ☐ Meals and any participant medications are arranged for

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Nursing Flow Sheet for Visits on Harkness 10

Protocol Name:
CUIMC IRB #
CRR Protocol #:
PI:
Contact number:

Coordinators:
Contact number:

Time	Events	Procedures	Completed- RN initial	Completed – Coordinator
Add time	Patient is Admitted	Weight (scale, not bed): BP___ HR____RR____ Temp_____ Sp02_____		
Add time	EXAMPLE: Collect pre-dose PK			
Add time	EXAMPLE Place IV line			
Add time	EXAMPLE Begin study drug infusion. Record Start & Stop time on Source		Start time: End time: Flush start: Flush end:	
Add time	EXAMPLE: Observe patient for s/s adverse reactions for 4 hours post medication		Reactions noted? Y/N	
Add time	Discharge	Discharge order must be in prior to discharge.		