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PURPOSE: To provide safe and consistent medication administration guidelines for investigational and standard of care medications given on CHPS unit.

SCOPE: CHPS nursing staff

PROCEDURE: CHPS staff follows hospital policy regarding Medication Administration including but not limited to:

1. Medication Administration: HUP & CPUP Policy 4B-03-01.
2. Minimal and Moderate Sedation for Diagnostic or Therapeutic Interventions: HUP & CPUP Policy: 01-12-11
3. Chemotherapy: Medication Use: HUP & CPUP Policy 01-12-49.
4. Control of Schedule II-V Medications (Controlled Substances): HUP & CPUP Policy 1-09-14
5. Investigational Drug Policy: HUP & CPUP Policy 01-12-04.
6. All medications (both investigational and standard of care) administered to subjects during the CHPS visit need signed orders in EPIC. The study team is responsible for placing medication orders in EPIC. Details to be discussed during nursing worksheet review prior to in-service.
7. For investigational product administration on the CHPS Unit, a Beacon build is required.
 - a. For submission of oncology and non-oncology Beacon build requests, please visit www.med.upenn.edu/CHPS > CHPS Core Services > Research Nursing Core > Epic Beacon Info.
 - b. For those unfamiliar with Beacon, refer to the below Knowledge Links for instructions on how to create a Beacon build:
 - i. “PennChart Treatment Plans (Beacon) for Oncology Providers (COURSE HS.20001.item.pcbeacprovider)

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- ii. “PennChart Treatment Plans (Beacon) for Infusion Nurses (COURSE HS.20001.item.pcbeacnurses).
- iii. “PennChart Beacon for Non-Oncology Providers (COURSE HS.20001.item.ipnononcol)

8. CHPS does not accept paper medication orders.
9. Medications must be prepared, verified, and labelled with appropriate medication label in IDS prior to administration on CHPS.
10. Label should be compatible with Bar Code Medication Administration Scanner.
11. CHPS Staff will administer the amount of IP On the label, the dispensed product should not be in excess of the dose listed on the label.
 - a. In the event of an infusion-related reaction, the full dose of IP may be withheld with the guidance of the study team
12. For all ~~research~~ oral investigational medications given on the CHPS unit, the CHPS nurse must administer the first dose to the participant, unless the route is out of their scope of practice (ex. intra-pleurally). There must be an order in Beacon for this first dose. Subsequent doses of this same investigational medication, if being taken while on CHPS, can be self-administered by the participant and a Beacon order is not needed.
 - a) As a point of clarity: If a participant receives the first dose of their oral investigational medication outside of the CHPS unit and thereafter takes it as a home medication, subsequent doses on the CHPS unit can be self-administered and do not require a Beacon order.
 - b) A separate Willow order is needed for doses being given outside of CHPS.
13. On the CHPS unit, CHPS nurses will administer all medications unless the route is non-standard (i.e. something other than oral, intravenous, subcutaneous, or intramuscular such as intra-pleural or intrathecal administration) OR requires specific training from the sponsor. In those cases, the study team nurse or physician will administer the medication on CHPS.
14. For patient safety, CHPS will perform a Point of Care urine pregnancy test for women of child-bearing potential before an investigational product (IP) is administered on the unit. This includes all IPs administered by CHPS staff as well as by study team members. If the study involves more than one visit per week and the IP is oral, a POC urine pregnancy test only needs to be performed prior to the first administration and weekly thereafter.

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a.

- b. In accordance with Hospital and Laboratory Accrediting Agencies and Federal and State regulation, all laboratories testing within a Medical Center environment must be performed under CLIA certification. (HUP/CPUP Policy 1-12-54); CHPS complies with this policy.
 - i. CHPS pregnancy tests have routine Quality Control checks
 - ii. CHPS staff are required to pass yearly education on their use.
 - iii. The pregnancy test result is documented in EPIC.
- c. CHPS does not accept study-sponsored and/or study coordinator-performed urine pregnancy tests on days IP is being administered because CHPS is unaware of that particular study team's urine pregnancy tests quality control checks, mandated education, user competency, test timing, and documentation.

15. Unused IP should be retained by the study team and not left on the CHPS unit. For the specific processes related to unused IP, please contact Investigational Drug Services.

16. In the event of an infusion-related reaction on the CHPS unit, the CHPS RN will stop the infusion and assess the patient. According to the nurse's judgment, a Rapid Response or a Code may be called. The CHPS staff will communicate with the study team in to inform them of the situation. The PI may be asked to come assess the patient on the unit and provide clinical guidance.

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