
Institutional – Policy**CC.P.153**

SUBJECT/TITLE: **Clinical Trial Standard of Care and Specialty Medication Procedures**

PURPOSE: To define how Standard of Care treatments and Specialty medications will be provided for investigational studies at UI Health Care, and to ensure applicable policies and procedures will be followed in the provision of these medications.

SCOPE: UI Health Care: Research

DEFINITIONS:

POLICY:

- A. Any medication noted as standard of care will be dispensed from UI Health Care supply, regardless of reimbursement by the sponsor. This includes chemotherapy or immunotherapy medications.
1. Medications handling is in the Procedures section below.
- B. Studies requiring specific preparations not consistent with UI Health Care practices, that do not allow dose rounding or require lot number and expiration tracking will be required to provide the study medication directly or provide funds to the Investigational Drug Service (IDS) for purchase and utilize the IDS Pharmacy.
- C. Per policy, [CC.P.152 White-, Brown-, and Clear-Bagging of Medications for Ambulatory Patients](#), no patient personal medications will be filled at an outside pharmacy and sent directly to the hospital or clinic by that outside pharmacy.
1. Investigational or Clinical Trial Medications that require sourcing from a non-UI Health Care specialty pharmacy for dispensing for home use are required to ship the medication directly to a subject's home.
 2. The UI Health Care Investigational Drug Services pharmacy will not maintain records related to any medications that meet this criteria.
 3. The patient may be asked to maintain a medication diary. Any diaries of this type will be maintained and stored by the study coordinator. No documentation will be maintained by IDS.
 4. Left over medications, if not returned to the sponsor/specialty pharmacy may be disposed of through IDS for a fee.

PROCEDURES:

A. These medications will be handled in the following manner regardless of payor:

1. Medications will be dispensed, prepared, administered and destroyed according to applicable UI Health Care institutional standards and practices.
2. When investigational medications are prescribed per policy CC.P.98, Prescribing Medications for Hospitalized Patient (Inpatients) and Clinic patients, dose rounding will be applied.
3. Lot numbers and expiration will not be captured for the medications.
4. No accountability records will be completed for the medication.

REFERENCES:

Source: Department of Pharmaceutical Care

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Date Reviewed: