| Clinical Research Center Medication Administration and Flush Terminology | CR-503 |
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| Clinical Research Standard Practices | **Effective Date:** September 2024 |

**SCOPE AND PURPOSE** This document is applicable to the following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

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| X | Principal Investigator | | Regulatory Specialists |
| X | Sub-Investigators | X | Key Study Ancillary Personnel |
| X | Study Coordinators/Associates | | Financial Analyst/Contract Management Accountants |
| | Data Specialist | | Central Research Office Personnel |

This SOP ensures safe and consistent medication administration for investigational and standard care medications in clinical research settings.
This document outlines the standard practices and procedures for administering medications, including investigational products (IPs), at the Clinical Research Center (CRC) of Penn State Health Milton S. Hershey Medical Center.

This SOP may be shared with Sponsors and/or CROs upon request.

**POLICY AND PROCEDURE STATEMENTS**

1. Medication Administration.
    a. All medications (oral, subcutaneous, intramuscular, intravenous, and inhalation) must have a paper order that is signed by the Principal Investigator or Sub-Investigator for the CRC nurses to administer.
    b. Medications need to be prepared, verified, and labeled by the Investigational Drug Service (IDS).
    c. CRC nursing staff will administer the exact amount of IP specified on the label. Any oral medication from the IDS pharmacy may be self-administered by the participant. Non-nursing staff may not administer any medication.
    d. A point-of-care urine pregnancy test will be completed per protocol guidelines. The test result will be recorded on the paper medication order or protocol-specific worksheet.
    e. Infusion-related Reactions: The CRC nurses will follow the CRC General Order set, notify the PI or sub-investigator, and activate the emergency response as needed

2. Medication Flush and End of Infusion (EOI)
    a. EOI Definition
        i. EOI is reached when the full volume of the study drug on the IV bag label has been infused.
        ii. If the study protocol EOI definition differs, it will be recorded on the protocol-specific worksheet.
        iii. Exception: If the full IP volume is reached but drug remains in the IV bag, EOI is reached when the remaining drug is infused and the bag is empty.

b. Flush
    i. Following the EOI, an additional 25 or 30 ml of diluent is infused through the IV tubing. The start and end times of the flush can be documented on the protocol-specific worksheet.

**RELATED POLICIES AND REFERENCES**
Chemotherapy and Biotherapy Policy (M-40 CPM)

Medication Administration (M-1 CPM)

Ordering and Dispensing Investigational Drugs (1414 PAM)

**APPROVALS**

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