**Example of Work Instructions for Investigational Product Accountability**

**I. Investigational Drug Accountability**

1. **Prior to Study Start**
   * Prior to IRB review, contact UNC Health Care Investigational Drug Services to obtain review and sign-off for a protocol involving the use of investigational drugs. All Requests for Investigational Drug Services must be made through the UNC Clinical Resource Management System (CRMS) available [here](https://irbis.research.unc.edu/crms/).
   * Confirm IDS is in receipt of the investigational drug prior to beginning the study.
   * Communicate discrepancies to the study Sponsor/supplier, if applicable.
2. **Investigational Drug Ordering**
   * Follow IDS procedures for protocol-specific ordering of the investigational drug. This may be done through EPIC or via paper orders.
   * The Investigator signing the drug order must be listed on the Form FDA 1572 or on the IRB application. Only qualified individuals (MDs, NPs, PAs) are permitted to sign drug orders.
   * Confirm with IDS the investigational drug supply is adequate and within expiration date. This will be verified and documented periodically throughout the study.
3. **Dispensing of Investigational Drug(s)**
   * IDS will dispense the drug in accordance with the protocol/pharmacy manual requirements.
   * A delegated staff member will pick-up the dispensed investigational drug from the designated IDS location.
   * The staff member will verify the information on the product provided matches the drug order placed.
   * The staff member will provide the investigational product to the study subject with the necessary instructions for using the product.
   * If applicable, instruct subject to return unused study medications and/or empty containers at their next study visit and document in the subject’s study file.
4. **Drug Return/Accountability**
   * Contact the subject before the study visit to remind them to bring in their unused medication and/or empty containers. Document this information in the subject’s study file.
   * At the study visit, collect unused study drug and/or empty containers per protocol. If applicable, review the subject’s drug diary and count the returned study drug quantity to verify subject compliance.
   * Document any discrepancies in drug accountability and re-educate subjects on proper instructions for use of the investigational drug, if applicable.
   * Return the unused drug to IDS.

**II. Investigational Device Accountability**

* + Follow UNC Health Care’s Investigational Devices Policy for Investigational Device Accountability. The policy can be found on the UNC Health Care Intranet or on [Research Central](https://irbis.research.unc.edu/crms/researchcentral/).