PURPOSE:
To delineate policies and procedures for investigators requesting a waiver of the UCI Health requirement to utilize Investigational Drug Service Pharmacy services for studies involving the use of investigational products.

DEFINITIONS:
1. **Institutional Review Board (IRB):** An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, reviewing, approving, and providing a continuing review of the trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial patients or healthy volunteers.

2. **Principal Investigator (PI):** An individual in charge of a clinical trial at a trial site. The Principal Investigator prepares and carries out the clinical trial protocol (plan for the study) or research. The principal investigator also analyzes the data and reports the results of the clinical trial.

3. **Sub-investigator (Sub-I):** Any individual member of the clinical trial team designated and supervised by the Principal Investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions.

4. **Informed Consent:** A process by which a patient or healthy volunteer voluntarily gives his or her permission to participate in a particular trial after having been in possession of all essential information necessary to make that decision to participate.

5. **Investigational product(s) (IP):** Any research medication, which will be administered under a specific research protocol, even if the medication is approved for marketing by the FDA.

6. **Drug accountability:** Involves all chain of custody documentation for an investigational product or drug receipt, storage, handling/preparation, dispensing, distribution, and return and/or destruction.
7. **Investigational Drug Service (IDS):** A specialized function of the Department of Pharmacy that provides oversight and support of all clinical trials involving investigational products to ensure patient safety, efficiency, and regulatory compliance.

**POLICY:**

1. All IPs must be under the oversight of the Investigational Drug Services (IDS) Pharmacy which includes all chain of custody documentation for the investigational product or drug receipt, storage, handling/preparation, dispensing, distribution, and return and/or destruction.
2. All UCI Health personnel involved with investigational products must comply with all federal and state regulations, in addition to all institutional policies and procedures.
3. All research teams utilizing investigational products in their clinical trials must use the IDS Pharmacy unless an IDS Pharmacy waiver was approved prior to the initiation of the clinical trial.
4. IDS Pharmacy waivers may be granted to only off-site locations (not located at the Orange Campus). Also, this waiver may be granted when the site can provide assurances during IDS onsite consultative review that procedures are in place to adequately manage the receipt, storage, handling, preparation, dispensing, distribution, security, return, and/or destruction for the investigational product(s), and one or more of the following is true:
   a. Timely delivery of investigational products by the IDS Pharmacy cannot be accomplished due to the location of the remote trial site (e.g., remote trial sites such as Irvine Campus, Hewitt Hall, or GHEI Clinics)
   b. The trial involves the use of an IP with a short stability
   c. The trial requires issuing the randomization number upon the patient’s arrival at the clinic
   d. The trial requires early morning or late evening patient appointments that are outside the current IDS Pharmacy hours of operation
e. The trial involves dispensing IP doses that are weight-based on the patient’s current actual weight upon checking into the clinic

5. The IDS Pharmacy Waiver must be renewed semi-annually after a site visit conducted by an IDS Pharmacist.

6. The PI shall notify IDS Pharmacy about any significant changes in the investigational drug management that may affect the waiver.

7. The IDS Pharmacy reserves the right to perform audits of storage, inventory, preparation, and dispensing conditions of waived trials.

8. Waivers may be withdrawn if serious deficiencies are noted upon audit

**PROCEDURE:**

The following procedures must be followed in order to obtain an IDS Pharmacy waiver for clinical research trials utilizing an investigational product at UCI Health:

1. The PI, Sub-I, or delegated research staff shall submit a written request to idsp@hs.uci.edu prior to the site initiation visit (SIV), which includes the following information or materials:
   a. IRB study number
   b. Study protocol
   c. Pharmacy manual (if available)
   d. Justification for the waiver request

2. An IDS pharmacy representative will:
   a. Review the request and perform a site visit within 14 business days of receipt to confirm acceptability of the waiver, or request additional information
   b. Communicate the outcome of the request to the PI and clinical coordinator within 3 business days of the assessment
c. Arrange the second site visit upon the study patient’s enrollment and receiving investigational product

d. Complete the IDS Pharmacy Waiver Review Form upon completion of the second site visit

e. Communicate final waiver status to the PI and clinical coordinator and upload a copy of the letter to OnCore

3. IDS Pharmacy will send a notification to the PI every six months prior to the onsite renewal.

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**Approvals:**

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