	Department of Pharmaceutical Services	
	Investigational Drug Service Standard Operating Procedure	
	IDS-SOP 01: Investigational Drug Training and Documentation	
	Version: 1	Date Reviewed: 22JAN2021

1) **Purpose:** To ensure all UCSF Investigational Drug Service (IDS) staff is appropriately trained according to federal and local regulations, institutional policies, ICH-GCP guidelines, and study protocol/Sponsor requirements.

2) Definitions and Abbreviations

Investigational drug: a drug that has not received FDA approval for commercial distribution, has been approved by the FDA for distribution under Treatment IND status, or has been approved for commercial distribution but is under investigation for an unapproved indication subject to a commercial or investigator-sponsored IND.

IDS: Investigational Drug Service

ICH-GCP: International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice. ICH-GCP guidelines describe the standard for the design, conduct, performance, monitoring, auditing, recording, analyzing and reporting of clinical trials.


IP: Investigational Product

IRT: Interactive Response Technology, including Interactive Web Response Systems (IWRS) and Interactive Voice Response Systems (IVRS), is utilized by research teams to manage study patients and investigational drug supplies.

Vestigo®: Vestigo is an electronic, web-based application used by IDS to manage drug accountability and billing. Vestigo is compliant with Part 11 of Title 21 of the Code of Federal Regulations.


3) Training

- a) Professional licensure for all pharmacy staff shall be active and current
- b) The following training modules or certifications shall be completed by the IDS staff during the orientation process and are repeated as specified by institutional policy:
 - i) Collaborative Institutional Training Initiative (CITI) Training
 - (a) Good Clinical Practice
 - (b) Human Subjects Protection Training
 - ii) Sterile compounding, including handling of hazardous compounds
- c) Additional training as required by the Department of Pharmaceutical Services will also be completed by the IDS pharmacy Staff

	Department of Pharmaceutical Services	
	Investigational Drug Service Standard Operating Procedure	
	IDS-SOP 01: Investigational Drug Training and Documentation	
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4) Responsibilities

- a) All IDS staff, consisting of pharmacists and pharmacy technicians, shall:
- i) Be aware of regulatory requirements and acceptable standard for the conduct of clinical trials and the protection of human subjects.
 - ii) Be familiar with the purpose of the study and the protocol and have access to protocol information.
 - iii) Have an adequate understanding of the specific details of the protocol and attributes of the investigational product needed to perform assigned tasks by the Primary Investigator.
 - iv) Be proficient in navigating and utilizing the inventory management application, Vestigo®
- b) The Lead IDS Pharmacist, as listed on the study's Delegation of Authority, is assigned to the protocol and shall be:
- i) The main contact in IDS for the study team and Sponsor, unless otherwise coordinated for backup coverage purposes.
 - ii) Competent to perform or have been trained to perform the tasks delegated by the Primary Investigator.
 - iii) Informed of any pertinent changes during the conduct of the trial and receive additional training as appropriate.
 - iv) Responsible for coordinating protocol-specific training for supporting IDS and non-IDS pharmacy staff, as necessary.
- c) Non-IDS staff will only support medication management and study patient dispenses within their scope of practice and with specific guidance and oversight from IDS Pharmacy staff.
- d) Sponsor or sponsor representative is responsible for providing pharmacy-specific documents (e.g. protocol, investigator brochure, pharmacy manual), protocol-specific training and study-related access (i.e. IRT) for the Lead Pharmacist.


	Department of Pharmaceutical Services	
	Investigational Drug Service Standard Operating Procedure	
	IDS-SOP 01: Investigational Drug Training and Documentation	
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5) Procedures

- a) Initial training of IDS Pharmacists and IDS technicians will include all relevant trainings included in Section 3 of this document and review of IDS specific policies and SOPs.
- b) Sponsor required protocol training will only be completed by Lead Pharmacist.
- c) Initial protocol-specific Lead Pharmacist training may be instructor-led or through self-training:
 - i) Instructor-led: Training may be conducted by the Sponsor or its representative (i.e. Clinical Research Associate) during the Site Initiation Visit (SIV).
 - ii) Self-instruction: The Lead Pharmacist will review study-provided training and protocol information and prepare dispensing and inventory management instructions for supporting IDS pharmacists and technicians in Vestigo.
 - iii) The Lead pharmacist may also complete assigned on-line training coursework or attend web-based training sessions related the study.
- d) Ongoing Lead Pharmacist training will be completed with new amendments or updates throughout the study conduct, as provided by the Primary Investigator, study coordinator, or Sponsor
 - i) Review is required for modifications to the protocol, investigator's brochure, pharmacy manual, or package insert that affect the investigational product management, preparation, or disposition.
 - ii) Lead Pharmacist is responsible to review changes and update Vestigo and shared resources available to support staff accordingly.
- e) Documentation of required training, initial and ongoing, completed by the Lead Pharmacist may include one or more of the following:
 - i) Sponsor Site Initiation Visit log
 - ii) Sponsor Delegation of Duties log
 - iii) Other Sponsor format, including web-based platform (i.e. Shared Investigator Platform, ICON)
 - iv) Email affirmation of training on specific materials.

	Department of Pharmaceutical Services	
	Investigational Drug Service Standard Operating Procedure	
	IDS-SOP 01: Investigational Drug Training and Documentation	
	Version: 1	Date Reviewed: 22JAN2021

- f) The Lead Pharmacist will prepare a protocol summary to facilitate the training of IDS and non-IDS Staff. They are also responsible for ensuring that the training material is up to date.
- g) The Lead Pharmacist will provide training to IDS Pharmacy Staff
 - i) Training may be instructor-led by the Lead Pharmacist in person directly to IDS staff, ad-hoc, during regularly scheduled staff meetings, or self-directed by instructions prepared by the Lead Pharmacist
 - ii) IDS Staff are trained to dispense investigational products and can support protocol dispensing for all IDS protocols and are trained by the protocol-specific Lead Pharmacist
 - iii) Dispensing and inventory management instructions are available to IDS Pharmacy staff in Vestigo
 - (1) The electronic capture of IDS Pharmacy staff credentials in Vestigo is utilized to confirm that they are trained in accountability and dispensing procedures
- h) The Lead Pharmacist will provide training to non-IDS Pharmacy staff, as needed, for weekend and off-hours dispensing and protocol management
 - i) Training may be instructor-led by the Lead Pharmacist in person directly to non-IDS staff, ad-hoc, during regularly scheduled staff meetings, or self-directed by instructions email to non-IDS staff
 - ii) The training will ensure that key parts of the protocol and pharmacy manual that a verifying or dispensing pharmacist must follow to successfully dispense investigational product are included
 - iii) The step-by-step IP preparation instructions are included on the production label (label that prints with each dispense) to instruct staff how to prepare the product
 - iv) Non-IDS staff is required to review the relevant information provided prior to verifying or dispensing IP. Documentation of training is captured in the following manner:
 - (1) Order verification: Verifying pharmacist(s) is captured in Epic©
 - (2) Compounding: The compounder signs the production label (or captured in Epic)
 - (3) Final check: The pharmacist(s) signs the production label (or captured in Epic)
- i) Changes to institutional policy that may affect investigational product disposition or management will be discussed with the Sponsor before implementation and updating Vestigo instructions

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6) Related Policies or SOPs

- a) Administrative Policy [6.07.05 Medication Management: Investigational New Drugs IND](#)

7) References

- a) Kay SC, Luke DG, Tamer HR. ASHP guidelines for the management of investigational drug products. Am J Health-Syst Pharm. 2018;75(8):561-73.
- b) Amin SR, Lee JS, Avila JG, Boron MJ, Conley S, Enos R, et al. HOPA investigational drug service best practice standards. Hematology/Oncology Pharmacy Association. 2014.
- c) International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use. Glossary. <http://ichgcp.net/1-glossary>.

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Document Revision History			
Version Number	Section	Description of Change	Justification of Change
1.0	All	New Document	N/A