



INVESTIGATIONAL DRUG SERVICE (IDS) Standard Operating Procedures

The Investigational Drug Service (IDS) strives to meet or exceed the standards of *Good Clinical Practice* (GCP).

1. UC Davis Health (UCDH) policy requires that distribution of all investigational drug products is coordinated and supervised by the Investigational Drug Service.

Shipping Address (for ALL IDS shipments):

UC Davis Health
Investigational Drug Pharmacy, Rm **DT0762**
2315 Stockton Blvd
Sacramento, CA 95817

IDS Pharmacy Locations & Contact Information:

Central IDS Pharmacy

UC Davis Health
Investigational Drug Pharmacy, **Rm 1107**
2315 Stockton Blvd
Sacramento, CA 95817
hs-ids@ucdavis.edu

Cancer Center IDS (IDSCC) Pharmacy

UC Davis Comprehensive Cancer Center
Investigational Drug Pharmacy
4501 X Street, **Rm 1008A**
Sacramento, CA 95817
hs-idsc@ucdavis.edu

Central IDS Phone: 916-703-4093

Central IDS Fax: 916-703-7048

IDS Cancer Center Phone: 916-734-7176

IDS Cancer Center Fax: 916-734-2260

2. **Staffing and hours (appointments required)**

Central IDS Hours: Monday – Friday 8:00 am to 4:30 pm
Extended hours by prior arrangement only (closed weekend and holidays)

IDSCC Hours: Monday - Friday 9:00 am to 4:30 pm (closed weekends and holidays)

A hospital pharmacist is available to address urgent IDS issues 24-hours a day by calling the 24-hour inpatient pharmacy at **916-703-4084**. For non-urgent issues, after regular hours of operation, a voice message may be left at the Central IDS number: 916-703-4093.

Central IDS Staff

Patrick J. Febre, PharmD	pjfebre@ucdavis.edu
Kimmie V. Nguyen, PharmD, BCPS	rxknguyen@ucdavis.edu
Peter B. Trovitch, PharmD	ptrovitch@ucdavis.edu
Nikki Cargill, PhT	dlcargill@ucdavis.edu
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Cancer Center IDS (IDSCC) Staff

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Jessica Turner, CPhT	jturner@ucdavis.edu

Assistant Chief Pharmacist, Oncology and Investigational Drug Services

Andrea Iannucci, PharmD, BCOP	aaianucci@ucdavis.edu
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3. Security

The Central IDS Pharmacy is located in a safe and secure location inside the main hospital at UC Davis Health. It is located behind double locked doors. The door to the pharmacy is locked and only accessible to pharmacy personnel via a passcode. The Cancer Center IDS Pharmacy is located in a safe and secure location inside the Cancer Center. It is located behind double locked doors. The door to the pharmacy is locked and only accessible to pharmacy personnel via badge scanner and passcode. Visitors are permitted to enter the IDS pharmacy area only when escorted by IDS or other pharmacy personnel.

4. Technology Protection

The UCDH IDS complies with Federal Regulations (FDA 21 CFR Part 11) that govern the use of computerized systems (e.g. IXRS). PIN numbers, access codes, etc., are not shared without written approval from the sponsor.

5. Drug Storage

Investigational drugs are appropriately stored in accordance with Good Clinical Practice Guidelines and the study protocol. Study drugs are stored separately by protocol and are not co-mingled with non-study drugs. Returns are isolated.

In accordance with Hospital Policy 1623, partial and/or used vials of cytotoxic and hazardous investigational drugs will be destroyed after compounding.

6. Temperature Management

The UCDH IDS adheres to institutional policies regarding medication storage and temperature control. IDS medication refrigerators and freezers are maintained in accordance with UCDH Patient Care Standard IV-57: Refrigerator/Freezer Requirements for Medications, Patient Nutrition and Laboratory Specimens and Controls. Temperature logs are kept for all refrigerators and freezers where investigational drugs are stored. The refrigerator and freezer temperatures in both the Central IDS and IDSCC are continuously monitored with a remote device (**Aeroscout**) capable of recording and storing minimum and maximum temperatures and/or with an audible alarm. Refrigerator and freezer monitors in the IDS areas are equipped with calibrated monitoring tags that are replaced annually. An electronic record of the temperature is taken every 20 minutes. If a temperature excursion results in the refrigerator or freezer temperature going out of the acceptable range, a page is sent to the Medication Security Pharmacist (or to a pager located in the 24-hour inpatient pharmacy, when the Medication Security Pharmacist is off duty). Using the Aeroscout system ensures that IDS gets immediate notification when temperature excursions occur and can send pharmacy staff to IDS to investigate the device and resolve any issues (e.g. open door) or relocate medications if necessary.

Metasys system serves as the back-up refrigerator monitoring system and is managed 24 hours a day by our Plant Operations and Maintenance (PO&M) department. In the event of a system failure with Aeroscout, IDS will utilize Metasys. Because Aeroscout sensors are mobile, they may be more susceptible to variations in temperature related to the position of the device. If the Aeroscout system reports an excursion, IDS may defer to the information provided in the Metasys report to determine whether the device was truly out of range.

Room temperature in both the Central IDS and IDSCC pharmacies is electronically monitored 24 hours a day and is maintained within acceptable limits by the PO&M department, in accordance with UCDH Policy 1689: Temperature, Humidity and Air Exchange Monitoring and Control. This monitor is also calibrated annually. Records of automated temperature logs are maintained by the UCDH Plant Operations and Maintenance (PO&M) department.

In addition, the Central IDS staff keeps a manual temperature monitoring log daily, excluding weekends and holidays when the IDS is closed. The manual temperature log documents the date, temperature, and initials of the recorder. Sponsor's temperature logs are not used. Electronic logs are available for email, upon request. Please allow a minimum of 5 business days to receive these logs.

Corrective action is taken and documented for any temperature excursion outside of the acceptable range. Sponsors are notified according to protocol instructions and all drug(s) will be quarantined until approved for use.

Acceptable temperature ranges:

Room temperature	68 to 75°F
Refrigerator	36 to 46°F
-20°C Freezer	5 to -13°F
-70°C Freezer	-79.6 to -126.4°F

For more information regarding temperature management, please refer to PCS Policy IV-57.

7. Power Supply

The primary power source for the IDS is the UCDH PO&M power plant. In the event of power failure, UCDH has two backup power sources. If UCDH PO&M fails, power is pulled from SMUD (Sacramento Municipal Utility District). If SMUD is unable to supply power, UCDH additionally has generators to power all critical systems. All the refrigerators and freezers are part of the critical systems.

8. Receiving and Transport

All investigational drugs are received by the Central IDS Pharmacy (the “control” pharmacy). When study drugs are to be dispensed from one of the satellite pharmacies, the drugs are moved to that area by IDS pharmacy personnel, or study personnel. Appropriate records of the move are kept by both the control and satellite pharmacies (consistent with NIH guidelines).

Drugs are kept within the acceptable temperature range during transport. The IDS provides the following equipment: insulated containers, ice packs, dry ice. The IDS requests that sponsors supply any additional necessary equipment required for transport.

The satellite pharmacy keeps records of receipt (from the IDS) and records of drug disposition. At the conclusion of dispensing, all documents are forwarded to the IDS for inclusion in the study file.

Prescriptions may be filled in IDS but dispensed by the investigator. Authorized study personnel may pick up filled prescriptions in IDS or prescriptions may be delivered to the investigator by IDS staff. All prescriptions not dispensed directly to the patient will be dispensed in a sealed transport container.

If permitted by the protocol, and if requested by the investigator, prescriptions may be sent by FedEx, UPS, USPS, or the courier service in compliance with all of the above.

9. Dispensing and Labeling

Investigational drug dispensing meets all safety requirements provided by pharmacy law for non-investigational drugs. Each dispensed medication is labeled with a standard prescription label in addition to the sponsor’s label (if any).

Study drugs may be dispensed directly from the Investigational Drug Service to the investigator, study personnel or to the participant. Study drugs may also be dispensed from one of the inpatient or outpatient pharmacies. There are 3 inpatient pharmacies (one of which is a 24-hour pharmacy) and 6 outpatient pharmacies (including the UCDH Cancer Center Infusion Pharmacy and the CCRC). These areas are referred to as “satellites.” The IDS works with the study staff to develop a safe and efficient dispensing plan.

Standard expected preparation and dispensation times for study drugs are as follows:

Oral preparations (simple)	1 hour
Oral preparations (complex and compounded)	2 hours
Parenteral preparations (biohazard and injectable)	2 hours

10. Drug Accountability Record Form (DARF) Documentation

The IDS will record required information on the DARF for sponsor-provided study drug. NCI DARFs will be used unless otherwise required by the sponsor. If the sponsor-provided study log has not been furnished to IDS by the time of study drug receipt, the NCI DARF will become the default log and will be used for the entirety of the study. Should locally-sourced commercial drugs be used in study participants, details about the drugs, including but not limited to the manufacturer, lot number, and expiration date will not be proactively recorded and retained by the IDS. UCDH's internal policy requires the recording of manufacturer, lot number, and expiration date during dispensing. This information may be made available upon written request in the event of drug recall, regulatory agency inspection, and adverse event reporting.

11. Inventory

Current and accurate inventory and dispensing records are kept for all study drugs. A monthly drug inventory is conducted in both the Central IDS and IDSCC pharmacies.

12. Expired Investigational Product Quarantines

The IDS quarantines any drug that will be expiring by the following process:

- 1) The IDS tapes the expiring/expired kits in a bag, and using a permanent marker label as "Quarantined - Do Not Dispense"
- 2) IDS documents the quarantine on the DARF, which includes the lot numbers, number of kits quarantined, who quarantined them, and the date.

13. Patient-Returned Study Medication

All patient-returned study medication bottles, packaging, and extra medication must be returned to the IDS within a timely manner for reconciliation and appropriate destruction/disposal. Patient-returned study drug must be provided to the IDS with the accurate return date, study name, and subject ID/MRN. The IDS will log the date and count of patient returns as required by the provided DARF(s). Non-cytotoxic drug supplies may require the UCDH research coordinator to provide the pill count to IDS.

14. Drug Destruction/Disposal

Medication vials, once used, opened, or emptied, will not be retained, but rather will be disposed of as waste to minimize personnel and environmental exposure to substances. The IDS will not document destruction of partial vials, including the volume disposed of, after use for compounding. Destruction forms will be generated for destroyed patient-returned study medications. Unless explicitly required by the study, IDS will utilize a tech check tech process for destruction of patient returns.

University California Davis Health (UCDH) has a permit from the Department of Public Health to use an outside agency for the disposal (incineration) of hazardous and/or medical waste. If "on site" destruction is requested for unused medication, the medication is incinerated by our contracted service unless other instructions are given. Medication bins sent for incineration are barcoded prior to leaving UCDH for tracking purposes. Upon request, the IDS can supply a date of incineration. Medication is sent to the following location for incineration:

Clean Harbors
1021 Berryessa Road
San Jose, CA 95133
EPA ID: MAD039322250

Destruction as well product returned to sponsor will not occur without prior written authorization from the sponsor. All destruction and product return will be documented. If the sponsor does not provide a destruction form, the IDS will use internal destruction forms.

15. Hazardous Drugs

The IDS pharmacies will operate in accordance with USP General Chapters <797> and <800>. USP <800> outlines practice measures and standards for handling hazardous drugs and to promote the safety of patients and healthcare personnel, and environmental protection. The IDS pharmacies have adopted practices

consistent with USP <797> and <800> to reduce hazardous drug exposure in the healthcare setting. All individuals, including sponsors and monitoring personnel, who dispense, perform drug accountability, or otherwise manage the inventory of hazardous study drugs must carry out their duties as is consistent with the requirements of USP <800>. This includes but is not limited to individuals donning proper personal protective equipment when handling hazardous drugs and outlined precautions to prevent environmental exposure and/or contamination. Instructions and adequate supplies will be provided to sponsors and monitoring personnel at each visit to the UCDH IDS to ensure adherence to UCDH IDS standards. Failure to comply with requirements will result in the termination of the monitoring visit.

16. Estimates

IDS will provide estimates of fees upon request. The start-up and close-out fees are one time, non-refundable fees. The start-up, annual maintenance and close-out fees are non-negotiable. Additional charges may apply. These fees will be agreed upon prior to the initiation of pharmacy study set-up by IDS and study activation.

17. Study Documents

Electronic copies of all study documents must be sent to IDS. Current and previous versions of the study protocol may be kept electronically on our secure, limited access shared drive. Sponsors and study personnel are required to notify IDS in writing via email when study document modifications occur and must provide IDS with electronic copies of such modified study documents.

18. Randomization

Upon request, the IDS will prepare a randomization schedule using a program (Research Randomizer) that uses a JavaScript random number generator to produce customized sets of random numbers.

19. Blinding

Unblinding envelopes (if used) are kept in the Central IDS where they are secure yet available 24-hours a day, if needed in an emergency. Protocol guidelines will be followed in the unlikely event that it is necessary to unblind a treatment. Study drug and study documents are not accessible to blinded study personnel.

20. Training and Delegation Logs

A "Signature and Training Log" of all individuals who dispense or otherwise manage the inventory of study drugs is kept in each study binder. The sponsor's log may be used if one is provided. The IDS provides training for all pharmacists and technicians who participate in the study (all individuals who dispense or otherwise manage the inventory of study drugs). The IDS pharmacist prepares protocol-specific written instructions that provide pharmacy personnel with information on proper dispensing and preparation procedures.

Training record forms will be completed by the IDS only if provided and/or requested by the Sponsor. Otherwise, initials, signature, and dating on the UCDH IDS Pharmacy Signature Log will serve as evidence of self-training.

Delegations logs will be signed by essential and relevant IDS staff only, as determined by the IDS.

21. Archiving

To comply with ICH E6; section 8.2-8.4 (Essential Documents for the Conduct of a Clinical Trial), and as required by the applicable regulatory requirements, after completion or termination of the trial, all pharmacy documents will be forwarded to the investigator, who will be responsible for retention.

22. Monitoring Visits

All visits will occur at the Central IDS Pharmacy. Review and collection of IDS documents is the responsibility of the Monitor/CRA during a scheduled onsite visit. The IDS cannot fax/mail/email IDS records. The IDS does not participate in remote monitoring visits. Access to sterile pharmacy areas (e.g. Infusion Center Pharmacy and main Central IV Admixture room) is prohibited.

Please reserve time for your monitoring visits at least one week in advance. Please specify the amount of time you will need for your visit, at the time of request. Monitoring visits must conclude within the scheduled appointment time. The IDS will not double book monitoring visit appointments. At the conclusion of your visit, we ask that you give an IDS staff member a verbal sign out report. An email sign out report should follow within 72 hours. Please allow 10 business days for query resolution. Charges per monitoring visit will be according to contract. The IDS has a 24-hour cancellation and rescheduling policy. If you miss your appointment, cancel or change your appointment with less than 24-hours notice, you will be charged for the full monitoring visit, per contract.

23. IRB Participation

An IDS Pharmacist can be a member of the IRB. The pharmacist is not listed on the FDA 1572.

24. Licensure and Curriculum Vitae (CV)

All UCDH pharmacists and technicians, including Investigational Drugs Service staff, are required to maintain an active California Pharmacist or Pharmacy Technician Licensure, in good standing, with the California State Board of Pharmacy (UCDH Department of Pharmacy Policy 256:00). Verification of pharmacist licensure is monitored by the UCDH Pharmacy Administration and Human Resources staff. Pharmacists and technicians are not permitted to work without evidence of current active licensure. Verification of pharmacist and technician licensure may also be viewed on the California Board of Pharmacy web page (www.pharmacy.ca.gov/online/verify_lic.shtml). Documentation of IDS pharmacy staff licensure will be provided upon request. Signed copies of IDS pharmacist CV's are maintained in the IDS pharmacy. Copies will be provided to the sponsors upon request.