

Investigational Drug Services

Why IDS?

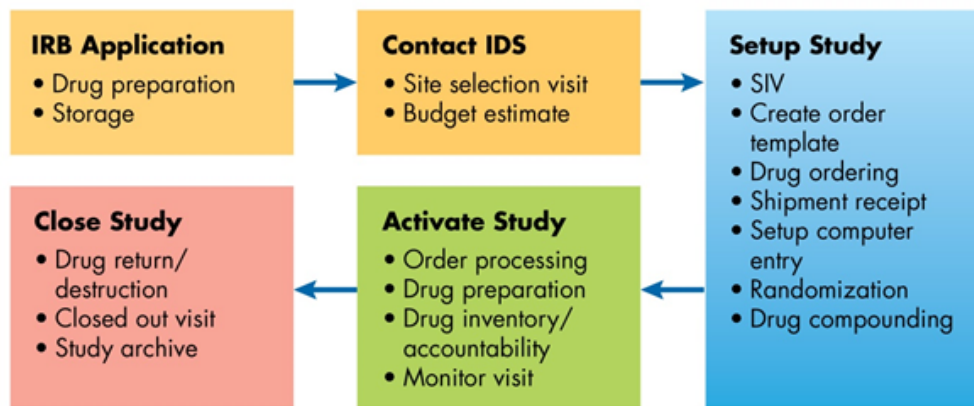
According to Code of Federal Regulation 21 CFR 312.62(2), an investigator is required to maintain adequate accountability records for the investigational drug or biologic. At UC Davis Health all investigational drugs or biologics (also known as "test articles") are handled by the **Investigational Drug Services (IDS)**, a Division of the Pharmacy Department. IDS manages the receipt, storage, dispense, return and disposal of study drugs in accordance with Good Clinical Practice Guidelines, the study protocol requirements, and all applicable rules and regulations.

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Read IDS Standard Operating Procedures

Includes contacts, staffing, hours, address and other helpful information ([here](#))

Overview of Investigational Drug Management process at UC Davis Health



IDS Fees

IDS Fees are estimated based on pharmacist's review of the initial protocol version. The estimate may change upon further review or amendments to study protocol.

For the rough estimate of fees, click [here](#)

For specific estimates, submit:

- Pharmacy Manual
- Investigator Brochure
- Protocol
- Filled out "IDS Study Start Up Worksheet"
- IRB approval (if available at that time)
- Consent Form (if available at that time)
- IWRS access (if available at that time)

Set-up Fee:

One time, non-refundable fee charged upon pharmacy study activation. Set-up fees include but are not limited to protocol review, site qualification visits, site initiation visits, development of study specific dispensing procedures, EMR entry and label design (mandatory), randomization (if needed) provision of GCP-compliant storage and inventory system including temperature monitoring, IXRS training/set-up, study drug supply security, creation of pre-printed prescription/order template, quarterly monitoring visits, first year study drug inventory, in-service training for essential pharmacy personnel, and drug destruction.

Annual Maintenance Fee:

Annual maintenance and inventory fees will be applied to multi-year studies on the anniversary of the pharmacy study activation date. The

Annual Maintenance Fee covers but is not limited to a monthly study drug inventory by IDS, study drug accountability, receipt and disposition, scheduled quarterly monitoring visits, temperature monitoring, and query responses.

Dispensing Fee:

Dispensing fees will be charged based upon protocol specific study drug dispensing requirements. Dispensing fees are charged for each prescription number generated. The estimate fee will be calculated based upon maximum chargeable cost per patient per pharmacy visit. Amount charged may be lower than estimated cost depending on actual prescribed dosage. UCDMC Investigator Initiated Trials will not be charged dispensing fees. Additional charges for shipping will apply.

Study Close-out Fee:

Study closure activities include but are not limited to return or destruction of study drug, archiving of study documents, final drug accountability and drug destruction (if needed), provision of outstanding documentation such as temperature monitoring logs, accountability logs, final billing if outstanding balance remains, and storage of protocol specific documents.

Distribution and Maintenance of Investigational Product

IDS stores and dispenses drugs in accordance with Good Clinical Practice Guidelines, the study protocol requirements, and all applicable rules and regulations. IDS is responsible for:

1. Establishment of Standard Operating Procedures (SOP) for each study
 - a copy for Sponsor
 - a copy for Investigator's file
2. Proper storage conditions
 - Temperature logs
 - Documentation of excursions
3. Segregation of study agents by protocol
4. Isolation of expired and damaged study agents

The IDS maintains an inventory of each investigational drug stored in the pharmacy. This record (**Drug Accountability Form** or DARF) contains:

- Drug's name, dosage form, strength, lot number and expiration date.
- Dispensing Information:
 - Date
 - Subject info (ID, initials, etc)
 - Dose
 - Quantity dispensed/received/wasted
 - Balances
 - Signature/initials

The IDS also maintains randomization codes of patients receiving the drug when applicable. As a rule, treatment should not be unblinded except under emergency conditions, which are typically described in the protocol. Before unblinding, the process should be discussed with the study sponsor.

At the conclusion of the study, the pharmacist returns, transfers or disposes of all unused investigational drugs according to the specific instructions provided by the sponsor or sponsor-investigator. IDS follows sponsor instruction for disposal/destruction documented in the Investigational Agent Disposition Record.

Prescribing and Dispensing of Investigational Drugs and Biologics

Only authorized prescribers will prescribe investigational medication. The prescribers must be listed on the FDA Form 1572 and IRB Research Personnel List. Prescription for investigational medication must contain ALL information currently required by state, federal and institutional laws and policies. The information include name & address of patient; name & quantity of drug; date of issue; typed or printed name, address and phone number of prescriber; signature of prescriber.

Prior to the pharmacy dispensing properly prepared study medication(s), they must verify that:

- The subject has signed the informed consent document
- The study protocol is available in the pharmacy
- The protocol is currently approved by the IRB
- Drug information is available in the pharmacy
- There is a valid and complete physician's order for the investigational agent.
- The prescription label for an investigational drug will be marked "For Investigational Use Only"

The prescription label for an investigational drug will be marked "*For Investigational Use Only*"

UC Davis Health Policy and Procedure 1508 "[Investigational Drug Distribution](#)" (section III) defines the "administration" of the drug as "the direct application of the drug to the body of the patient or research subject by injection, inhalation, ingestion, or other means." Specifically, section IV, part H, states that "only physicians, nurses, and authorized licensed personnel will dispense and/or administer investigational drugs and biologics." In addition, teaching patients to administer (self-administer) a drug or biologic must be done by licensed personnel. Unlicensed personnel (CRCs) may pick up the investigational drug from the IDS in tamper-proof packaging and deliver it to the patient.

Dietary Supplements

IDS may dispense dietary supplements if the research involves the use of a supplement to treat a disease (intended for use in diagnoses, cure, relief, treatment, or prevention of disease or intended to affect the structure or function of the body), or involves significant risk to subjects. If any of the above criteria are met, the FDA requires submission of an IND (Investigational New Drug) Application. For studies under [Investigational new Drug Applications](#) (INDs), the supplement is treated as investigational drug.

Compounding Investigational Drugs

In a continuing effort to implement the compounding provisions of the Drug Quality and Security Act (DQSA, 2013), the FDA issued several policy documents regarding compounded drugs for human use. The documents describe the FDA's expectations regarding compliance with current good manufacturing practice (CGMP) requirements for facilities that compound human drugs.

If the investigational product of a study is an outsourced compounded drug, the facility must either be a drug manufacturer registered with the FDA or a pharmacy that is registered with the FDA as a 503b outsourcing facility. UC Davis Health Department of Pharmacy is registered as 503A facility, which can compound drugs pursuant to a prescription to UC Davis patients.



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