



Investigational Drug Services

The Investigational Drug Service (IDS) of the Morehouse School of Medicine is responsible for the consistent and centralized management of pharmaceutical/investigational drug protocols used in human subject research, at all sites under the Clinical Research Center (CRC). The Investigational Drug Service serves as the management unit for the storage, dispensing and disposal of study medication for many clinical trials. It ensures standardization of procedures within each protocol, and further protects human subjects who participate in research protocols, through improved drug safety and accountability measures.

Investigational Drug Services	Rate	Comments
Study Initiation		See below*
• Simple	\$3000	• Simple studies are defined as studies in which investigational products (IP) are utilized in the outpatient setting and do not meet specific criteria for complex studies.
• Complex	\$4500	• Complex studies are defined as studies in which IP are requiring non-sterile/sterile manipulation or special handling. • Example: Reduced dosing due to impaired kidney function
Study Maintenance	\$250/mo	See below*
Study Closeout	\$500	See below*
Dispensing Fee		• Fees are charged at the time of dispense of medications
• Simple	\$60	
• Complex	\$200	
• IV Infusion	\$200	
• IV Bolus	\$75	
Patient Return Fee	\$45	• Unused medications should be returned to the Midpoint and End of dosing (EOD) visit
Monitoring Visits	\$100/hr	• The purpose is to determine compliance with protocol and regulatory requirements and with study policies and procedures

Description of Services

Study Initiation:

- **Fees are charged for the work of setting up a study and of performing necessary staff training which include:**
 - Review protocol and prepare budget
 - Drug Build and Reviews
 - Orderset reviews
 - Meet with sponsor or investigator
 - Receive and process initial shipment of study drug
 - In-service staff (as needed)
 - Prepare study fact sheet and drug information fact sheet for pharmacy staff and nursing staff (as needed)

Study Maintenance:



- Maintain appropriate inventory storage, study records
- Update ordersets/review based on amendments
- Order and receive inventory
- Process expired inventory and patient returns
- Store patient returns
- Periodic study billing

Study Closeout:

- Process study records to archive
- Meet with participant for closeout visit
- Final billing
 - Additional cost: Process study drug for Return to sponsor/ destroy on-site