Department of Pharmacy Services

UNIVERSITY of VIRGINIA HEALTH SYSTEM

Updated Investigational Drug Services (IDS) Fees

Following a review of our fees, UVA IDS pharmacy has updated current fees and added an extensive amendment fee. A separate fee structure to address the complexity of platform and umbrella trials and the increased workload associated with those trials has also been included. This fee structure will be effective March 1, 2024. These updated fees will apply to new trials with an initial startup occurring after March 1, 2024. Initial startup is defined as the date IDS feasibility review is requested in CRConnect. The fee structure will not be retroactive. For any trial that has already received an IDS feasibility review in CRConnect, please utilize the previous fee structure for estimating your start-up costs. These updated fees take into account increased costs that have occurred since the last fee update in July 2016. For your convenience, we have attached the fee structure here. It is also available on the Investigational Drug Services Pharmacy website, here.

Standard trial fees

The IDS fees are separated out by sponsor/funding source as outlined here*:

Study Type	Initiation Fee	Maintenance Fee	Extensive Amendment Fee	Bulk Product compounding	Pharmacy closeout
Industry-sponsored	$6,000	$150/month	$900	$150/hour	$300
Investigator-initiated	$300	$30/month	$45	$35/hour	$75
Foundation Group	$600	$50/month	$90	$75/hour	$125
Federal Group	$600	$50/month	$90	$75/hour	$125
Cooperative Group	$300	$30/month	$45	$35/hour	$75
Biosafety Level 1 or 2†	$6,500	$225/month	$975	$150/hour	$400

**Any shipping fees, FDA-approved drugs, supplies, or other equipment which must be purchased by IDS will also be charged to the study.*

†These agents must be registered with UVA's Institutional Biosafety Committee (IBC) Institute. For classification information, please refer to the CDC-NIH's guidance document, Biosafety in Microbiological and Biomedical Laboratories (BMBL) or visit UVA's Biosafety website

Questions? Please contact John Parker at HAP7KW@uvahealth.org

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Master Protocol Trials††

The IDS fees are separated out by sponsor/funding source as outlined here*:

Study Type	Initiation Fee	Maintenance Fee	Extensive Amendment Fee	Bulk Product compounding	Pharmacy closeout
Industry-sponsored	$7,800	$195/month	n/a	$150/hour	$390
Investigator-initiated	$390	$40/month	n/a	$35/hour	$100
Foundation Group	$780	$65/month	n/a	$75/hour	$165
Federal Group	$780	$65/month	n/a	$75/hour	$165
Cooperative Group	$390	$40/month	n/a	$35/hour	$100
Biosafety Level 1 or 2†	$8,450	$300/month	n/a	$150/hour	$520

**Any shipping fees, FDA-approved drugs, supplies, or other equipment which must be purchased by IDS will also be charged to the study*

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†† Includes trials, like Platform, Umbrella, and Basket trials, that have a single master protocol but can involve 1 or more interventions in multiple diseases or a single disease.

Categories of cost are as follows:

INITIATION FEE: A one-time charge at study initiation. This charge is incurred regardless of whether a subject is ever enrolled into the study. This includes the cost of preparing a preparation/dispensing procedure, planning or initiation meetings, staff in-services for pharmacists and technicians, setting up order sets or treatment plans, and Vestigo study management

MAINTENANCE FEE: This includes quality assurance, monitor visits, restocking, dispensing, and reordering as needed. Maintenance fees continue until the sponsor grants permission for pharmacy to close, study is closed to enrollment, enrolled patients have completed treatment, and all investigational product is returned or destroyed.

EXTENSIVE AMENDMENT FEE: Amendments that include onboarding new drug, new orders/new order sets, and/or new treatment plans, or significant treatment plan edits.

BULK COMPOUNDING: Bulk compounding of capsules, tablets, suspensions, gels, repackaging, etc, including over-encapsulation for blinding purposes.

PHARMACY CLOSEOUT: This fee covers the closeout visit (if applicable), destruction or return of investigational product, preparing the study documents for long-term storage and long-term storage fees.

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