

CENTRO COMPRENSIVO DE CÁNCER

UNIVERSIDAD DE PUERTO RICO

MEMO

To all employees


Dr. Luis A. Clavell Rodríguez
Executive Director

Clinical Trial Standard Fees

Administrative start-up fee

For all clinical trials sponsor shall pay CCCUPR a non-refundable administrative start-up fee of \$2,000. The Non-refundable Start-Up payment is used to cover the costs associated with the study's set-up activities. This fee covers start up time dedicated to setting up services for the program, site initiation meetings and or activities, cost of preparing and submitting regulatory documents and account creation to ensure clinical trial billing compliance. The Non-refundable Start-Up fee should be payed upon execution of the Clinical Trial Agreement, Sub award or Study Contract. A one-time start up bill will be send once the clinical trial is signed and received.

Pharmacy fees

If the approved study requires the use of investigational drugs that must be stored and dispensed through UPRCCC facilities or are included in a study in which UPRCCC is the grantee organization, an Institutional Pharmacy Start-up Standard Fee and monthly storage fees will apply. An initial set-up fee is applicable when the study requires one or more of the following 1) request for a pharmacist to be assigned to the study 2) preparation of study records for dispensing 3) request for usage of storage space and 4) dispensing of study drug to participants. Monthly billing begins once the investigational product is received and will continue for as long as the project is active. A Pharmacy termination fee shall apply whenever there is a request for close out.

*Start-up costs will be based on time and effort dedicated by Research Pharmacist, type of investigation drug and study protocol.

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A summary of fees is shown in the table below

Study Phase	Description of Service	Fee
Initiation*	Protocol review by staff Development of Study Enrollment Orders, labels and dispensing documents Develop physician order forms Activities related to arrangement of space and equipment for drug storage Training of staff on study protocol	\$3,000- \$6,000 per study protocol
Maintenance	Drug dispensing Drug storage and inventory Create reports of drug usage and dispensing as required Maintain study records as required Take part in study meetings as required Prepare for site visit as required	\$38.00 per month
Termination	Perform study closeout as required by each sponsoring agency Contacting sponsor for drug return Remove Investigational Drug and related records Package and shipping residual or unused drugs for return	\$2,000

*Start-up costs will be based on time and effort dedicated by Research Pharmacist, type of investigation drug and study protocol.