



COST ESTIMATE REQUEST FORM

*Please complete the entire form so the Research Pharmacy may provide you with a cost estimate.
Return the completed form to researchpharmacy@columbia.edu as an e-mail attachment or fax to 201-305-0068.
Include a copy of the protocol if not submitted prior.*

IRB # _____ (if available)

Contact Information:

Investigator: _____ Phone: _____

Fax: _____ E-mail: _____

Coordinator: _____ Phone: _____

Fax: _____ E-mail: _____

Administrator: _____ Phone: _____

Fax: _____ E-mail: _____

Important: If the listed "Administrator" is to serve as point-of-contact for receiving study invoices and billing information, please list this same point of contact for the "Principal Investigator Designee"

Study Title: _____

Study Description: (check all that apply) Inpatient Outpatient Multicenter

On Call Study: Yes No *Weekend or Holiday dispensing?* Yes No

*****A study is considered on call if there is a possibility for dispensing outside of normal business hours (M-F 8AM-4PM). There is an additional fee for this service. *****

Department:

- | | |
|--|---|
| <input type="checkbox"/> Biochemistry & Molecular Biophysics | <input type="checkbox"/> Pediatrics - Allergy |
| <input type="checkbox"/> Biomedical Informatics | <input type="checkbox"/> Pediatrics - Biomathematics |
| <input type="checkbox"/> Dental Medicine | <input type="checkbox"/> Pediatrics - BMT |
| <input type="checkbox"/> Dermatology | <input type="checkbox"/> Pediatrics - Cardiology |
| <input type="checkbox"/> Genetics & Development | <input type="checkbox"/> Pediatrics - Clinical Genetics |
| <input type="checkbox"/> Medicine - Cardiology | <input type="checkbox"/> Pediatrics - Critical Care |
| <input type="checkbox"/> Medicine - Digestive & Liver Disease | <input type="checkbox"/> Pediatrics - Education |
| <input type="checkbox"/> Medicine - Endocrinology | <input type="checkbox"/> Pediatrics - Emergency Med |
| <input type="checkbox"/> Medicine - Experimental Therapeutics | <input type="checkbox"/> Pediatrics - Endocrinology |
| <input type="checkbox"/> Medicine - General Medicine | <input type="checkbox"/> Pediatrics - Gastroent. & Nutrition |
| <input type="checkbox"/> Medicine - Hematology | <input type="checkbox"/> Pediatrics - General |
| <input type="checkbox"/> Medicine - Infectious Disease | <input type="checkbox"/> Pediatrics - Hematology |
| <input type="checkbox"/> Medicine - Molecular Medicine | <input type="checkbox"/> Pediatrics - Infectious Disease |
| <input type="checkbox"/> Medicine - Nephrology | <input type="checkbox"/> Pediatrics - Molecular Genetics |
| <input type="checkbox"/> Medicine - Oncology | <input type="checkbox"/> Pediatrics - Neonatology |
| <input type="checkbox"/> Medicine - Preventive Medicine & Nutrition | <input type="checkbox"/> Pediatrics - Nephrology |
| <input type="checkbox"/> Medicine - Pulmonary, Allergy & Critical Care | <input type="checkbox"/> Pediatrics - Neurology |
| <input type="checkbox"/> Medicine - Rheumatology | <input type="checkbox"/> Pediatrics - Oncology |
| <input type="checkbox"/> Microbiology & Immunology | <input type="checkbox"/> Pediatrics - Pulmonary |
| <input type="checkbox"/> Neurology | <input type="checkbox"/> Pediatrics - Rheumatology |
| <input type="checkbox"/> Neuroscience | <input type="checkbox"/> Pharmacology |
| <input type="checkbox"/> Neurosurgery | <input type="checkbox"/> Physiology and Cellular Biophysics |
| <input type="checkbox"/> Obstetrics and Gynecology | <input type="checkbox"/> Psychiatry |
| <input type="checkbox"/> Ophthalmology | <input type="checkbox"/> Mailman School of Public Health |
| <input type="checkbox"/> Orthopedic Surgery | <input type="checkbox"/> Radiation Oncology |
| <input type="checkbox"/> Otolaryngology / Head & Neck Surgery | <input type="checkbox"/> Rehabilitation Medicine |
| <input type="checkbox"/> Pathology | <input type="checkbox"/> Surgery |
| <input type="checkbox"/> Anesthesiology | <input type="checkbox"/> Urology |
| <input type="checkbox"/> ICAP | <input type="checkbox"/> Emergency Medicine |
| | <input type="checkbox"/> Herbert Irving Comprehensive Cancer Center |

Funding Source:

Sponsor: Investigator Initiated NCI SWOG CCG COG

Pharmaceutical Industry Sponsored:

Spon Name _____ Spon Prot # _____

Spon ContactName _____ Phone _____

Fax: _____ E-mail: _____

Services requested: (check all that apply)

Dispense: Capsules/Tablet Patient Kit IV Product Pre-filled Syringes

Ointment/Cream Other _____

Delivery: *(There is an additional fee for this service)*

Are deliveries to hospital or clinic sites required? Yes No

If yes, specify delivery location(s) (Building, Flr, Rm) _____

Where will patients be seen (Clinic location)? _____

Drug Product Ordering: Yes No (Investigator must complete Drug Requisition Form Attached)

Drug Returns: (Investigator, if unsure, check with study sponsor):

No drug returns to Research Pharmacy, Investigator will oversee drug return and destruction via OSHA, EPA, DEA compliant methods

Used drug supplies will be returned to Research Pharmacy for immediate destruction

Used drug supplies will be returned to Research Pharmacy for storage and reconciliation by study monitor, and then destruction or return to sponsor

Used drug supplies generated in the pharmacy must be stored in the Research Pharmacy for reconciliation by study monitor, and then destruction or return to sponsor

Randomization:

There is no randomization

Randomization will be managed by the Investigator and the Research Pharmacy will be notified of treatment assignment in writing on drug order or via separate FAX

Randomization will be managed by the Research Pharmacy via an Interactive Voice Recognition System (IVRS)

Randomization will be generated by the sponsor or Investigator and managed by the Research Pharmacy via paper copy or on-line randomization method

Randomization code will be generated by the Research Pharmacy managed within the Research Pharmacy

Inventory:

Inventory will be handled by the Research Pharmacy using standard GCP compliant methods

Inventory will be handled by the Research Pharmacy using Sponsor specific inventory forms

Inventory will be handled by the Research Pharmacy using Sponsor specific inventory forms and IVRS

Drug Description: *Anti-Neoplastic Agent(s)*? Yes No

Study Drugs: (include investigational agents to be dispensed in the study)

Study drug provider: _____

Formulation: (check all that apply)

Capsules Tablet Vials Pre-Packaged For Dispensing

Bulk (Requires Packaging/Labeling/Dispensing)

Storage: (check all that apply)

Room temp 2-8°C < -10°C < -70°C Other _____

Study Drugs requested to be sourced by Research Pharmacy:

(include investigational agents & FDA approved drugs that are to be purchased and dispensed by the pharmacy)

NOTE: Research Pharmacy-sourced investigational agents or FDA approve drugs are not subject to returns; this includes any expired/unused supply that is purchased or sourced by Research Pharmacy for a study.

Study team acknowledgment regarding Research Pharmacy drug purchase:

As part of the Cost Estimate agreement, if The CUIMC Research Pharmacy agrees to procure drug(s) for the conduct of a trial, it is done so with the understanding that the sponsor and the study team agree and acknowledge the following:

-Drugs may only be available in bulk volume and prices are subject to change based on the cost, on the day of purchase.

-Drugs may be purchased in advance, to ensure availability at time of patient enrollment.

-Sponsor agrees to pay for total cost of purchased drugs, regardless of whether it is utilized or not.

-Sponsor agrees that refunds or returns are not allowed for any expired or unused drugs.

-The CUIMC Research Pharmacy does not carry a readily available supply of commercially available medications. When drugs are purchased for a trial, it is done so with the understanding that enough supply must be procured for subjects, to ensure site does not come across shortage issues throughout the course of the trial.

Select if statement has been read & acknowledged? YES NO

Study drug(s) & FDA approved agents to be sourced via Standard of Care:

Additional Items/Equip Required: IV Pump Injection supplies Ordering Bulk Drug

Other _____

Item/equipment provider: _____

Additional Info: Has Project been submitted to IRB? Yes No

Will study be submitted to the Clinical Trials Office? Yes No

Anticipated Start Date: _____ Approx duration: _____

Estimated # of patients _____

Monitoring:

Investigator will monitor Research Pharmacy function directly without outside monitoring

Sponsor will not monitor Research Pharmacy function

Sponsor will monitor Research Pharmacy function

Monitoring performed by: Sponsor CRO/SRO Other _____

Monitoring Company Name/Div _____

Monitor Name _____ Phone _____

Fax: _____ E-mail: _____

The following number of outside monitoring visits are expected each year _____

Effective February 1st, 2022, a new fee schedule has been implemented. This is applicable for all cost estimate requests submitted to the research pharmacy on or after February 1st, including new studies related to prior ones, such as studies involving subsequent phases or long-term monitoring. The prior fee schedule will continue to be honored for studies that are active prior to February 1st, 2022.

Invoices will be e-mailed to the Principal Investigator for pre-approval. Invoices may also be e-mailed to one (1) additional person named as Principal Investigator Designee, if desired. If you wish to name a Principal Investigator Designee for this protocol, please provide us with the following.

Name of "Principal Investigator Designee"	Email

The listed "Principal Investigator Designee" will be the point-of-contact for receiving study invoices and billing information. If this information changes throughout the duration of study, please email IDS-Billing@columbia.edu

The Research Pharmacy will not provide services until the signed cost estimate and regulatory documents (IRB approval letter, 1572 form) have been received.

When you are ready to initiate the study, please notify the Research Pharmacist named on the cost estimate.

Thank you.