



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:** _____

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"/> Urology |

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 both investigational agents and FDA approved products)

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 _____

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

☐ Other _____

Items/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 _____.

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 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.