



**COST ESTIMATE REQUEST FORM (ver 050502)**

*Please complete the entire form so the Research Pharmacy may provide you with a cost estimate.  
Return the completed form to [researchpharmacy@columbia.edu](mailto:researchpharmacy@columbia.edu) as an e-mail attachment or fax to 201-568-6148.  
Include a copy of the protocol if not submitted prior.*

**IRB #** \_\_\_\_\_ (if available)

**Contact Information:**

**Investigator:** \_\_\_\_\_ **Department:** \_\_\_\_\_

**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

**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 \_\_\_\_\_

**Manufacture:**  Capsules  Patient Kit  IV Product  Ointment/Cream

Other \_\_\_\_\_

**Delivery:** (It is recommended that study staff p/u drug product from the pharmacy, when possible)

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)?

***Shipments:***

Are patient or clinic shipments required?  Yes  No

**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)

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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 \_\_\_\_\_

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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 \_\_\_\_\_.

**Meetings:**

Will there be a study start-up meeting for pharmacy to attend?  Yes  No

If yes, provide location, date & time (if known) \_\_\_\_\_

Will there be periodic study meetings for pharmacy to attend?  Yes  No

If yes, provide location, date & time (if known) \_\_\_\_\_

**Updates and Closure:**

Please notify the pharmacy of changes in study protocol and approval.

The pharmacy must also be notified when the study closes.

***You will receive a Research Pharmacy Cost Estimate within 1-2 weeks.***

***\*\*Complete and sign the Investigator Approval section, and return the signed copy to [researchpharmacy@columbia.edu](mailto:researchpharmacy@columbia.edu) as an e-mail attachment or fax to 201-568-6148.***

***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.***