CUMC Research Pharmacy
17 Smith Street
Englewood, NJ 07631
201.568.6315 Tel
201.568.6148 Fax
www.researchpharmacy.org

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 ***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)

____

____

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_________________.

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 ***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.