COLUMBIA UNIVERSITY MEDICAL CENTER

CUIMC Research Pharmacy
Milstein Hospital Building
177 Fort Washington Avenue, Suite MHB-LL1-001
New York, NY 10032
212.305.9867 Tel 212.305.0068 Fax

Submission Date: ☐
MM/DD/YYYY

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.
Include a copy of the protocol if not submitted prior.
Please allow up to 2 weeks for the review process. This time may be longer if Research Pharmacy is waiting for clarification from the study team or sponsor.

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) and Observed Holidays. There is an additional fee for this service. *****

Department:

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

Funding Source:

_____

_____

Sponsor: ☐ Investigator Initiated ☐ NCI ☐SWOG ☐CCG ☐COG ☐Federal
☐ 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: (Delivery service only available for Oncology studies or On-Call Services)
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
(If YES, complete ***Study Drugs requested to be purchased and dispensed by Research Pharmacy*** on next page)

Drug Returns: (Investigator, if unsure, check with study sponsor):
Used drug supplies will be returned to Research Pharmacy for immediate destruction

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

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

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

Study Drugs: (include all agents that are to be dispensed by Research Pharmacy 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 ☐< -20°C ☐< -70°C ☐ Other_____

Study Drugs requested to be purchased and dispensed 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 & the study team agree & acknowledge:

DRUG PROCUREMENT by RESEARCH PHARMACY *memo (page 5)*

Select if memo has been read & acknowledged? ***YES*** ☐ ***NO*** ☐

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

(include study agents that will be sourced & dispensed as standard of care by NYP Hospital & not through Research Pharmacy)

_____

_____

Additional Items / Equipment Required Notice:
Research Pharmacy ***only*** *dispenses research medications. All ancillary supplies such as needles, IV pumps, pill cutters, oral syringes, etc. must be provided by the sponsor or purchased by the study team. All these items are to be stored & handled by the study team.*

COLUMBIA UNIVERSITY
College of Physicians and Surgeons
In affiliation with NewYork-Presbyterian Hospital

RESEARCH PHARMACY
Clinical Trials Office
177 Fort Washington Ave, Suite MHB-LL1-001
New York, NY 10032
212.305.9867 Tel
researchpharmacy@columbia.edu

March 1st, 2024

Re: Drug Procurement by Research Pharmacy

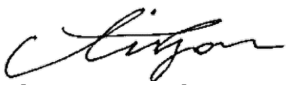
To Whom It May Concern:

The CUIMC Research Pharmacy (RP) is an investigational drug service established solely to serve the research needs of Columbia's investigators. As such, the RP does not maintain commercial stock of any pharmaceuticals, and any medication necessary for research will need to be provided or otherwise procured. When medications are procured by the RP, it is done so for that specific trial.

Our strong preference is for Sponsors to provide any medication that is required for the conduct of research, including any commercially available medication that is expected to be dispensed by the RP. If the RP agrees to procure drug(s) for the conduct of a trial, as confirmed as part of the Research Pharmacy Cost Estimate agreement/process with the Columbia research team, the agreement is done so with the understanding that the Sponsor and the research team agree and acknowledge the following:

a. Drugs may only be available in bulk volume and can only be purchased in the package sizes that are available. As a result, some drugs may not be utilized by the study and the RP and Columbia must be reimbursed for the full cost of drug purchased.
b. Prices are subject to change based on the cost, on the day of purchase. The RP will procure drug based on the research need, regardless of the price, and the RP and Columbia must be reimbursed for the full cost of drug purchased.
c. Availability is subject to change based on the distributor's inventory, and it may be affected during supply shortage.
d. The RP will procure drug based on the research need, with the understanding that enough supply must be procured for subjects to ensure site does not come across protocol compliance and shortage issues throughout the course of the trial. The RP and Columbia must be reimbursed for the full cost of all drugs purchased. For example: 1. Drugs may need to be procured prior to randomization and depending on the randomization, drug may not be utilized. 2. Drug may need to be procured in advance of multiple visits and depending on if the patient visits occur, drug may not be utilized.
e. Drug procurement can take 2-6 weeks depending on the distributor and the approval process. To ensure availability of supplies upon subject enrollment, the Research Pharmacy will procure the initial supply when the clinical trial agreement is executed. This may be prior to any subject screening.
f. Drug refunds or returns to the supplier are not allowed by the supplier.
g. Sponsor agrees to pay for total cost of procured drugs, regardless of utilization.
h. Any expired or unused supply will be shipped back to the sponsor or destroyed per our SOP.

Thank you,



Elnaz Anjom, Pharm.D

Senior Director of Research Pharmacy

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

Will study be submitted to the Clinical Trials Offices? ☒ ***Yes*** ☐ ***No***

Anticipated Start Date:_____Approx duration:_____

Estimated # of patients_____

Is this study being conducted under a CU Faculty-Held Investigational New Drug (IND) application? Yes ☐ ***No*** ☐ If **yes**, please list **all** products that are covered under the IND (i.e., all drugs that are listed in the IND May Proceed or IND Acknowledgment Letter)

_____

_____

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.