



KIT PACKAGING COST ESTIMATE REQUEST FORM

Please complete the entire form so the Research Pharmacy may provide you with a kit packaging plan and cost estimate. Return the completed form to researchpharmacy@columbia.edu as an e-mail attachment or fax to 201-568-6148.

IRB # _____ (if available)

Contact Information:

Investigator: _____ *Department:* _____

Phone: _____ Fax: _____

E-mail: _____

Coordinator: _____ *Phone:* _____

Fax: _____ E-mail: _____

Study Title: _____

Study Description: _____

Number of Sites: _____

Total Number of Patients: _____

Comment: _____

Randomization:

- There is no randomization
- Randomization will be generated by the sponsor or Investigator
- Randomization code will be generated by the Research Pharmacy

Describe Randomization Scheme:

Describe Treatment Groups:

- 1- _____
- 2- _____
- 3- _____
- 4- _____

Kit containing clinical supplies:

Describe Kit: _____

Services requested: (check all that apply)

Manufacture: Capsules Ointment/Cream Other _____

Capsule Filler: Lactose Riboflavin Microcrystalline Cellulose
 Placebo Tablet Other _____ None

Dosing Schedule:

Label Instructions: ex. *Take 1 tablet twice a day, as directed by MD.*

Treatment 1: _____
 Name of Drug

Please fill in all that applies to the study. If your study design does not fit well into this table, please make a table and attach.

Study Day									
Visit #	0	1	2	3	4	5	6	7	8
# of Bottles									
# of Tablets in Bottle									
# of Dose per Day									
# of Capsules per Day									
Time Doses are Taken Daily									

Treatment 2: _____
 Name of Drug

Please fill in all that applies to the study. If your study design does not fit well into this table, please make a table and attach.

Study Day									
Visit #	0	1	2	3	4	5	6	7	8
# of Bottles									
# of Tablets in Bottle									
# of Dose per Day									
# of Capsules per Day									
Time Doses are Taken Daily									

Treatment 3: _____
 Name of Drug

Please fill in all that applies to the study. If your study design does not fit well into this table, please make a table and attach.									
Study Day									
Visit #	0	1	2	3	4	5	6	7	8
# of Bottles									
# of Tablets in Bottle									
# of Dose per Day									
# of Capsules per Day									
Time Doses are Taken Daily									

Treatment 4: _____
 Name of Drug

Please fill in all that applies to the study. If your study design does not fit well into this table, please make a table and attach.									
Study Day									
Visit #	0	1	2	3	4	5	6	7	8
# of Bottles									
# of Tablets in Bottle									
# of Dose per Day									
# of Capsules per Day									
Time Doses are Taken Daily									

Drug Description:

Study Drugs: (include both investigational agents and any FDA approved products that will be provided in the kit)

Study drug provider: Sponsor Investigator
 Drug will be purchased via the pharmacy

Sponsor Contact: _____

Describe Formulation:

Capsules Tablets Vials Bulk (Requires Packaging/Labeling/Dispensing)

Drug shipment from the Research Pharmacy will be to:

Investigator/Coordinator Sites