

**** To ensure completion of the Pharmacy Review process, all Protocols involving pharmaceutical agents MUST be submitted to Pharmacy AT LEAST 4 WEEKS prior to REB deadline for receipt of application packages****

RESEARCH OPERATIONS PHARMACY ACCOUNTABILITY

1. To be completed by the Principal Investigator (type name):

SPONSOR (please put N/A if not applicable):

FULL STUDY TITLE:

Open Label **Single Blind** **Double Blind**

PHARMACY ROLE:			
Will there be a set of Preprinted Orders		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Are orders attached on HRH Template?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Is pharmacy involved in the following:			
• Receiving Medication		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Storing Medication		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Drug Counts		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Returning Medication		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Randomization of Study Participant		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Order Entry		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Site Coordinator Visit(s)		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• How is product dispensed:			
Drug Kit available		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> IV Preparation	<input type="checkbox"/> Oral		
• Daily Dispensing (Specify):			
• Other (Specify):			
• Drug Use:			
• Inpatient Use Only		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Outpatient Use Only		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Inpatient & Outpatient Use		<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Special Storage Requirements in Pharmacy?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, describe:			

	<input type="checkbox"/> Room Temperature	<input type="checkbox"/> Refrigeration	<input type="checkbox"/> Freezer
• Special Storage Requirements on units?			<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>If yes, describe:</i>			
	<input type="checkbox"/> Room Temperature	<input type="checkbox"/> Refrigeration	<input type="checkbox"/> Freezer
• Special Equipment Requirements?			<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>If yes, describe:</i>			
<i>Is the special equipment provided by the Sponsor?</i>			<input type="checkbox"/> Yes <input type="checkbox"/> No

STUDY DRUG INFORMATION:					
<u>DRUG NAME:</u>		Dosage form:		Route:	
Medication schedule:		Dispensed Frequency:		Dispensed by:	
Reconstitution (if applicable):		Stability:			
<u>DRUG NAME:</u>		Dosage form:		Route:	
Medication schedule:		Dispensed Frequency:		Dispensed by:	
Reconstitution (if applicable):		Stability:			
<u>DRUG NAME:</u>		Dosage form:		Route:	
Medication schedule:		Dispensed Frequency:		Dispensed by:	
Reconstitution (if applicable):		Stability:			

2. To be completed by Pharmacist:

DEPARTMENT OF PHARMACY INVESTIGATIONAL DRUG STUDY COST FINDER

(Revenue Cost Centre: _____ .12023)

PRE REB PROTOCOL REVIEW: RANGE \$500.00 - \$1,000.00 DEPENDING ON COMPLEXITY:	
<ul style="list-style-type: none"> • Review of protocol/meetings with investigator(s) • Completion of REB forms: Pharmacy Cost Finder, Investigational Drug Info form • Review Feasibility of Formulating Product/Placebo (blinding, placebo, physical stability studies) • Ad-hoc meeting and pre-initiation site visit 	\$
PHARMACY START UP FEE: Range \$500.00 - \$2,000.00	
<ul style="list-style-type: none"> • Write Dispensing Procedures • Preparation of randomization/enrollment table/worksheets/binders • Any manufactured item gets final batch preparation • Staff education i.e. study design/written pharmacy procedure • Preparation of Non-Marketed drug data sheet • Procurement/storage of drug supplies • Return/Destruction of drug supplies to sponsor at conclusion of study • Set up of Meditech directories/inventories • Initiation meeting, ongoing education, close out meeting 	\$
TOTAL FIXED STUDY COSTS	\$

MONTHLY FEE: Range \$50.00 – 130.00 / month	
<ul style="list-style-type: none"> • Maintenance and storage of inventory • Temperature Logs • Maintenance of drug accountability and records • Billing procedures • Ad hoc meetings with investigator(s), sponsors and suppliers • IVRS 	\$
Monthly Fee, if applicable, is: - included in Study Funding as per Clinical Trial Agreement (Budget/Schedule of Payments) <input type="checkbox"/>	
- to be Invoiced to Sponsor as per Clinical Trial Agreement (Budget/Schedule of Pmts.) <input type="checkbox"/>	

MISCELLANEOUS CHARGES	
<ul style="list-style-type: none"> • Call back fee (to be charged only if required) 	\$
Call Back Fee, if applicable, is: - included in Study Funding, as per Clinical Trial Agreement (Budget/Schedule of Payments) <input type="checkbox"/>	
- to be Invoiced to Sponsor as per Clinical Trial Agreement (Budget/Schedule of Pmts.) <input type="checkbox"/>	

PER DISPENSING VISIT COSTS		ARM 1 Cost/Dose	ARM 2 Cost/Dose	ARM 3 Cost/Dose
<i>Break down by study arm</i>	<i>Drugs:</i>			
IV PREPARATION COSTS				
<ul style="list-style-type: none"> • Manufacture of product/placebo including supplies/labour \$20.00 - \$30.00 / dose for oral or IV Intravenous dose preparation (guide \$1.00/minute) 		\$	\$	\$
DRUG ACQUISITION COSTS (for study drug, control arm drug and/or placebo)				
_____		\$	\$	\$
_____		\$	\$	\$
DISPENSING FEES - IV & ORAL DRUGS				
<ul style="list-style-type: none"> • \$15.00 / per dose 		\$	\$	\$
<ul style="list-style-type: none"> • Return of study drug for participant compliance (\$5.00/dispense as per protocol) 		\$	\$	\$
CLINICAL FEES:				
<ul style="list-style-type: none"> • Participant Counseling: \$15.00/dispense 		\$	\$	\$
<ul style="list-style-type: none"> • Participant Monitoring: \$10.00/dispense 		\$	\$	\$
TOTAL PER PARTICIPANT DISPENSING VISIT		\$	\$	\$

COMMENTS:

Principal Investigator's Signature

Date

Pharmacist's Signature

Date

Telephone
Extension

Print Principal Investigator's Name

Print Pharmacist's Name