RESEARCH PHARMACY IMPACT REVIEW AND BUDGET

Page 1 to be completed by the Principal Investigator or Study Coordinator and returned to

This must be completed prior to any contract negotiations or grant applications and submitted as part of local site materials to account for Research Pharmacy expenses.

In addition to completing the information below, please include the most recent version of the following documents:

- Protocol
- Pharmacy manual (*if available*)
- Investigator's Drug Brochure (*required for non-FDA approved drugs*)

Study Overview	
Principal Investigator (PI):	**Email:**
Study title:	
IRB Protocol # / Study Identifier:	
Research Coordinator:	**Email:**

Billing Contact Information ***(use non-profit corporation for industry or non-VA funded studies; use local VA Research Office contact for VA-funded studies)***

Name:

Email:

Study Estimates

Estimated number of subjects:

Estimated length of treatment or dispenses per subject:

Anticipated duration of study:

Anticipated treatment location(s):

List all **sponsor provided or study reimbursed** medications, supportive care/rescue medications, or supplies. Please list the medication dose, route, administration schedule, duration, and if any special handling or compounding is required.

List all drugs to be provided from the regular pharmacy standard stock or considered to be standard of care (include solutions, diluents, and non-prescription supportive care medications). Please list the medication dose, route, administration schedule, duration, and if any special handling or compounding is required.

Please respond to the following questions:

- Is this protocol considered standard of care? ☐ Yes ☐ No Comments/Notes:
- Will the VA be considered a satellite site of another institution? ☐ Yes ☐ No Comments:
  - If yes, please attach completed Letter of Understanding
- Is the investigator requesting to store investigational drugs outside of the Pharmacy Service? ☐ Yes ☐ No
  - If yes, a Delegation of Custody document is required. Provide rationale and information on expected storage location:
- Will mailing of investigational drug be required? ☐ Yes ☐ No
  - If yes, please describe the estimated number of mailing occurrences per subject:
- Will this trial require investigational drug dispensing outside of normal business hours? ☐ Yes ☐ No
  - If yes, please describe the anticipated need:

PRINCIPAL INVESTIGATOR SIGNATURE

By signing below, I acknowledge a proposed budget will be drafted by Research Pharmacy and will be submitted to applicable funding agencies for inclusion in contract negotiations and/or grant review.

Principal Investigator Date

RESEARCH PHARMACY IMPACT REVIEW AND BUDGET

Page 2 be completed by Research Pharmacy Staff and returned to Principal Investigator or Study Coordinator. This agreement must be completed prior to any contract negotiations or grant applications and submitted as part of local site materials to account for Research Pharmacy expenses.

Study Estimations

Estimated number of subjects:
Estimated dispenses per subject:
Anticipated duration of study:
Drugs provided by or reimbursed for by study:

Waiver Request

☐ If this box is checked, a Waiver of Investigational Drug Service Pharmacy Fees is requested. See justification below.

Justification:

Approved by: _____
Chief, Pharmacy Service or Designee Date

Estimated Charges – Fee for Dispensing Model

Activity	Fee	Estimate
Study Initiation and Close Out	$1500 / protocol	
Dispensing costs (*based on fee schedule*)	See comments section	
Maintenance (*to be billed starting annually after pharmacy initiation until pharmacy close out visit and final drug disposition occurs*)	$250 / year	
Other (*see comments section*)	See comments section	
TOTAL ESTIMATED IDS CHARGES		**$ 0.00**

Dispensing Fee Schedule:

Oral medication	$20	/dispense
IV push/SQ/IM	$35	/preparation
IV infusion	$45	/preparation
Hazardous IV infusion	$60	/preparation
Specialty compounding	$50-100	/preparation

Any additional supplies or non-standard of care medications required will be supplied by the PI or study sponsor. Above charges are estimates only. Final resolution of charges may exceed original estimate based on number of dispensings or preparations that occur.

Comments and IDS Pharmacist Sign Off

Research Pharmacist Date

Final Research Pharmacy Service Agreement Determination

☐ Our team has reviewed the above proposal and determined it will be of significant cost to Pharmacy Service.
The Pharmacy charges were assessed internally according to the Investigational Drug Service Impact Estimation Worksheet/Charges Worksheet and will be provided to the principal investigator for consideration in study budgetary discussions.

☐ Our team has reviewed the above proposal and determined that it will have an impact on Pharmacy Resources.
Due to the type of study (e.g., VA CSP, NCI-NCTN, etc), all pharmacy initiation and maintenance fees will be waived. View justification ab for further details.

☐ Pharmacy Service is not able to accommodate the requirements of this study at this time.
Comments:

☐ The cooperation of Pharmacy Service should be acknowledged in any publication which may result from this study.

Note: At the completion of the protocol, the Pharmacy Service is not responsible for the continuation of any study related medications. Once participants are no longer actively enrolled in the study, consideration of appropriate medical treatment will revert to standard of care.

_____
Chief, Pharmacy Service or Designee Date