

Department of Veterans Affairs

Memorandum

Date:

From: Research Pharmacist (119)

Subj: Pharmacy Reimbursement for Research Studies

To:

1. Attached are three documents. First is the estimate of pharmacy charges for your study entitled:

The second is a form for you to sign, which acknowledges the receipt of the estimate and agreement to authorize payment for the initiation of your study. The third document is an explanation of the various pharmacy charges.

2. Please note that it takes approximately 40 hours of time to implement the pharmacy portion of any study. Therefore, it will require a minimum of one week from the receipt of all drug/supplies and the sponsor's initiation visit before your study can begin accrual.

3. To avoid delay, please send the following information and documents to me as soon as possible. We will be unable to initiate your study until all of the following are completed and sent to the Research Pharmacist for our study file:

- a. The attached agreement form, completed.
- b. A listing of names and signatures of all personnel authorized to initiate treatment (or a copy of the FDA 1572).
- c. A list of the names and contact numbers of all study personnel.
- d. IRB approval document..
- e. Investigational Drug Data Sheet or a copy of the 10-9012 (Investigational Drug Information Record).
- f. A copy of the 10-1223 (Report of Subcommittee on Human Studies).

4. Please Note: In order to accommodate all investigators and insure timely handling of study maintenance, monitor visits to the pharmacy must be scheduled. Please have the monitor call to make an appointment.

5. If you have any questions about these documents or any other matters pertaining to the Research Pharmacy, please contact me at (410) 605-7113.

HAI YAN JIANG, R.Ph.

Attachments

Department of Veterans Affairs

Memorandum

Date:
From: Principle Investigator
Subj: Cost Memo for Human Studies Subcommittee
To: Research Pharmacist (119)

1. I have received the estimate for pharmacy participation in my study entitled:

The cost is

2. I have read the assumptions you have made in the preparation of this estimate and they are correct. I understand that if the sponsor or I change the requirements as outlined in these assumptions, the cost of the study may change as well.

3. I understand that I will be billed for the study initiation fee prior to the initiation of the study, and that I will be billed monthly after that for patients enrolled.

4. I understand that there will be a minimum of a one (1) week period after all drug/supplies are received and the site initiation visit occurs before patients may be enrolled in the study.

Signature:

Please Print Name:



DEPARTMENT OF VETERANS AFFAIRS

Maryland Healthcare System

Medical Center
10 North Greene Street
Baltimore MD 21201

Medical Center
9600 North Point Road
Fort Howard MD 21052

Medical Center
Perry Point MD 21902

Rehabilitation and

Extended Care Center
3900 Loch Raven Boulevard
Baltimore MD 21218

Outpatient Clinic
5510 West Shore Drive

Cambridge MD 21613

BASELINE FEE CATEGORIES

INITIATION FEE:

1. Review of protocol
2. Computer drug file entry and quick order set-up in CPRS
3. Dispensing Procedures
4. Randomization charts
5. Staff education
6. Estimate of pharmacy costs
7. Start-up meetings with sponsors and investigator
8. Initial receipt and labeling of clinical study supplies

MONTHLY ADMINISTRATION FEE:

1. Audits and monitors (interim and closure)
2. Documentation and ongoing drug accountability
3. Receipt and return of study drugs
4. Protocol changes
5. Study drug reordering
6. Periodic drug inventory

OUTPATIENT DISPENSING AND DOSE PREPARATION

This includes daily preparation, labeling and documentation of all study doses and prescriptions. Blinded and open study drugs will be dispensed and labeled in accordance with all hospital policies and state and federal regulations.

ESTIMATE OF PHARMACY CHARGES (SUMMARY)

PROTOCOL:

PRINCIPLE INVESTIGATOR:

DATE OF ESTIMATE:

PROJECTED ENROLLMENT: Number of Patients:

ITEM	CHARGE
Initiation fee	\$1,000.00
Yearly administration fee	\$ 800.00
Per patient enrollment fee	
TOTAL	

NOTES:

1. Initiation fee is required for the study to commence.
2. The patient fee will be billed monthly, based on the number of patients enrolled in the study per month.