Portland VA Medical Center

Financial Administrative Review of Research Proposals

**The Financial Administrative Review is the method the PVAMC uses to assess the costs of the clinical resources and the Principal Investigator’s protected time that is committed to a research project. Please submit completed forms to** **Research.Grants@va.gov****.**

**Investigator Name:**

**Project Title:**

**Funding Source:**

**Project Period:**

## SECTION I:

|  |  |  |
| --- | --- | --- |
| **PART A: Use of Research Pharmacy** | **Yes** | **No** |
| **1.0** | Will your study involve the use of the VA pharmacy? | [ ]  | [ ]  |
| If YES, you must submit your proposal and the investigational drug information record (VA Form 10-9012) to Sarah Happ, PharmD (extension 54757; sarah.happ@va.gov) to determine the total cost to the Pharmacy Service on a per patient basis and enter this information here. **Cost per patient:**      \*\*PLEASE attach the signed cost estimate worksheet from Pharmacy to this document\*\* |  |  |
| **1.1** | Does the funding source provide the drug under investigation at no cost to the PVAMC? | [ ]  | [ ]  |
| **PART B: Use of Pathology and Laboratory Services** |
| **2.0** | Will your study involve the use of the VA Pathology and Lab Service for collecting or performing tests on blood or body fluids, handling tissue or preparing slides, or processing, storing and shipping specimens to reference laboratories? | [ ]  | [ ]  |
| If YES, you must meet with Yan Chhai (extension 58344; yan.chhai@va.gov) to determine the total cost to Path and Lab on a per patient basis and enter this information here. **Cost per patient:**      \*\*PLEASE attach the signed cost estimate worksheet from Path and Lab to this document\*\* |  |  |
| **PART C: Use of Imaging Services** |
| **3.0** | Will your study involve the use of VA Imaging Services?  | [ ]  | [ ]  |
| If YES, you must contact Toni Anaya (extension 56512; toni.anaya@va.gov) to determine the total cost to Imaging on a per patient basis and enter this information here.**Cost per patient:**      \*\*PLEASE attach the signed cost estimate worksheet from Imaging to this document\*\* |  |  |
| **PART D: Other Medical Center Services** |
| **4.0** | Will your study involve the use of any other Medical Center Services not mentioned above (i.e., ophthalmology, sterile processing unit, etc)? [ ]  Yes [ ]  No**If yes,** please contact Research.Grants@va.gov for additional instructions. |
| **PART E: Use of Identifiable Data** | **Yes** | **No** |
| **5.0** | If you are using Medical Center Services, will the request for labs, drugs, x-rays, etc. be requested using the patient’s real name or will the request use a code?[ ]  Identifiable [ ]  Coded **PLEASE NOTE: For all requests that will use the patients real name, a research clinic must be established. Please contact Robert White (extension 56619;** **Robert.white2@va.gov****) to have a research clinic set-up.****Research Clinic Name (once clinic creation has been confirmed):**  |
| **PART F: Source of Research Subjects**  |
| **6.0** | **Will patients be enrolled from:**Inpatient services: Yes [ ]  No [ ]  Outpatient clinics: Yes [ ]  No [ ] Emergency care unit: Yes [ ]  No [ ] If **YES**, list services:       |
|  | Inpatient Enrollment: N/A [ ] , skip to 6.3 |
| **6.1** | Will patients be hospitalized for the sole purpose of participating in the research protocol? | [ ]  | [ ]  |
| **6.2** | Will research subjects be studied in any of the following settingsIntensive care unit Yes [ ]  No [ ]  # of days      Step down unit or monitored bed Yes [ ]  No [ ]  # of days      Bed on ward Indicate Ward       Yes [ ]  No [ ]  # of days       |
|  | Outpatient Enrollment: N/A [ ] , skip to 7.0 |
| **6.3** | Will outpatient      visits be held in an exam room/clinic [ ]  or PI’s private office [ ]  ? |
| **6.4** | If clinic indicate which one:       |
| **6.5** | Clinic location:       Length of Clinic Visit (research portion only):        |
| **PART G: Additional Information** |
| **7.0** | How many Portland VAMC patients will be enrolled over the life of the study?       |
| **7.1** | What is the maximum length of time a patient will be enrolled?       |
| **7.2** | On a per patient basis, what is the maximum number of individual clinic visits projected over the length of the study?       |
| **7.3** | On a per patient basis, how many of these visits represent additional outpatient visits scheduled solely as a result of the patient’s participation in the research protocol?       |
| **7.4** | Are there financial benefits to the Portland VA as a result of participating in this research (e.g., nursing support, laboratory tests, PI time volunteered to VA, free study drug to replace a drug used in standard of care)?  | [ ]  | [ ]  |
| If YES, please describe:       |  |  |
|  |  | **Yes** | **No** |
| **7.5** | Will the protocol involve patients hospitalized or recruited from outpatient clinics on a service other than your own (e.g., protocol from an investigator in Medical Service that would include patients from Psychiatry Service)? | [ ]  | [ ]  |
| If YES, which service is involved?      If YES, have you discussed this protocol with the Chief of that service? | [ ]  | [ ]  |
| **7.6** | Will the workload of fellows, residents, students, or nurses be impacted while caring for patients enrolled in your protocol? | [ ]  | [ ]  |
| If YES, have you discussed this with the Chief of the appropriate service?If YES, complete the following: Yes No Service(s)Fellows [ ]  [ ]       Residents [ ]  [ ]       Students [ ]  [ ]       Nurses [ ]  [ ]        | [ ]  | [ ]  |
| **7.7** | Will this project involve the Vancouver Nursing Home Care Unit?  | [ ]  | [ ]  |
| If YES, have you discussed this with the ACOS/Extended Care?  | [ ]  | [ ]  |

***(The following are examples of how to complete sections II. Replace each section with the information specific to your study. Add extra pages if necessary.)***

**Section II: All Aspects of Care Table: (Prepared by PI, see example below)**

S: Standard care, not reimbursed in budget

SR: Standard care, Reimbursed in budget

C: Research test performed at a Core laboratory (i.e., outside lab – not the VA lab)

RR: Research Related expense

A blank box would indicate that the test or procedure did not occur on the day or clinic visit in question.

List only encounters that will occur at the PVAMC. For laboratory tests, list all individual tests, not panels. For example, for drug screens, list all drugs for which you will test.

PLEASE NOTE: This section of the document is modifiable.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test/Procedure/Setting | Day1 | Day2 | Day3 | Day4 | Week1 | Week2 | Week3 | Week4 | Mo6 | Mo9 | Mo12 | Total RR | Total SR |
| Echo | S |  |  |  |  |  |  |  |  |  |  |  |  |
| ECG | S | RR | RR | RR | S | RR | RR | RR | S | RR | S | 7 |  |
| Holter Monitor | S |  |  |  |  |  |  |  | RR |  | SR | 1 | 1 |
| CT Scan | SR |  |  |  |  |  |  |  |  |  |  |  | 1 |
| Chest X-ray | S |  |  |  |  |  |  |  |  |  |  |  |  |
| ICU Bed |  | S |  |  |  |  |  |  |  |  |  |  |  |
| Blood Draw by VA Lab for Core Labs |  | C | C |  |  |  |  |  |  |  |  |  |  |
| Outpatient clinic |  |  |  |  | RR | RR | RR | S | S | RR | S | 4 |  |
| CBC |  | C |  | C | RR | SR | RR | SR | SR | RR | C | 3 | 3 |
| BUN |  | C |  | C | RR | SR | RR | SR | SR | RR | C | 3 | 3 |

## Costs will be calculated by each individual service using the Decision Support Systems (DSS) database

## Section III: Study Budget

You must submit a copy of the study budget showing the amount of funds that will be provided and on what timetable, even if the budget is still under negotiation.

If the grant is a yearly sum, a budget breakdown must be provided for each year. If funds are to be provided on a per patient basis, a payment schedule should be agreed to in advance with the funding agency and a copy of this should be included.

Indirect costs must be requested as per the policies of the institution that is administering the funds, i.e., OHSU or PVARF.

If allowed by the funding agency, salary should be requested for the PI and VA IRB fees should be requested.

Standard IRB fees for the VA IRB are:

Initial Review $3,000

Continuing Review $500

Amendments/Modifications $750

**Salary and IRB fees should always be requested from for-profit companies.**

**Budget page attached:** Yes [ ]  No [ ]  Not Applicable (Unfunded Study) [ ]

If no budget page is attached, and the study is funded, provide documentation, e.g., copy of subcontract from OHSU and explain below.

insert explanation here

**Will this work be done if the study is not funded?** Yes [ ]  No [ ]

If YES and Research Service determines that there will be research-related costs to the VA for this study, Research Service will seek permission from the PI’s Service Chief and/or the Executive Management Team (EMT) to allow the study to occur. **The study cannot begin without this approval.**