**Standard Operating Procedures (SOP)**

**Reimbursement of Research-Only Clinical Costs**

**Purpose**:

The purpose of this policy is to describe how funds are to be billed by and reimbursed to INSERT NAME OF VA FACILITY (VAMC) for non-standard of care clinic costs incurred in the conduct of an approved research study under administration by INSERT NAME OF LOCAL NPC (NPC).

**Scope:**

This policy applies to all approved research protocols conducted in the VAMC clinical setting, in which clinical care is provided for research-only purposes to meet the study criteria of patient participation. This does not apply to clinical activities considered “standard of care”, or care that would be provided absent the patient’s participation in the approved protocol, nor does it apply to unrelated, routine care provided to a patient during their participation in the study.

**Background**

As stated in VHA Handbook 1200.17, part 11.b.2, “*NPCS may reimburse VA for salaries and other costs incurred by VA in the conduct of VA-approved research projects or education activities. A VA medical facility may retain and use funds provided to it by the NPC. Such funds must be credited to the applicable VA appropriation account and available for account purposes without fiscal year limitations as provided for in 38 U.S.C 7364(b)(3)*.”

**Policy**

NPC reimburses VAMC upon receipt of an invoice for any procedures conducted for research purposes only.

The rate of reimbursement per procedure is determined by INSERT COST BASIS ONCE DECIDED BY VA. This cost basis will be provided by VAMC to NPC for purposes of building a comprehensive and accurate budget for each new project activated.

This cost table will be ratified annually by the Research and Development (R&D) Committee, who is responsible for reviewing and approving the Assessment of Clinical Impact for as part of the protocol submission to the Committee.

**Procedures**

VAMC will provide to NPC on an annual basis a cost table which includes current costs by procedure and CPT code.

NPC will conduct a review of the study documents upon receipt from the sponsor and ensure all anticipated procedures are included in the per-patient or total budget, based on the Schedule of Events, the protocol, and utilizing the cost table provided by VAMC.

The Principal Investigator (PI) will submit an Assessment of Cost Impact form as part of their project submission to the VAMC R&D Committee. The Cost Impact form must provide a listing of the anticipated research procedures, their corresponding CPT code, and the anticipated number of each procedure. MTRI will provide the PI with guidance on completing this form.

NPC will routinely, upon receipt of payment from the sponsor or prime, set aside funds as indicated on the approved Cost Impact form, and based on the above determined rates, into an account designated for VAMC reimbursement.

VAMC will generate, on an ANNUAL/QUARTERLY/MONTHLY basis, a bill of collection to be paid by the NPC. This bill of collection will include, but will not be limited to, an itemized listing of research-only services completed by VAMC during the invoice period and the study to which the cost is attributed. Items billed must agree with the Clinical Impact form approved by the R&D Committee. *(see alternative process)*

Upon receipt of the bill of collection, NPC will pay by check to VAMC the amount due from the designated account.

***ALTERNATIVE PROCESS (WHERE VAMC WILL NOT TRACK STUDY ACTIVITIES)***

*On an ANNUAL/QUARTERLY/MONTHLY basis, NPC will receive from the Study Coordinator, or Principal Investigator, documentation of all research-only procedures conducted during the study, listed by subject ID and the date of each procedure. NPC provides this information, along with a cover letter to VAMC Fiscal Management (or designated recipient determined by the local site) and requests a bill of collection.*

*Upon receipt of the bill of collection, NPC will pay the amount due by check to VAMC.*

***ALTERNATIVE PROCESS (FOR NPC WISHING TO USE A PERCENTAGE SYSTEM TO DETERMINE PAYMENT INSTEAD OF ITEMIZED COST)***

*NPC will determine the percentage of the total sponsor payment that is attributable to clinical activities to be performed by VAMC. For example, if the total paid per patient enrolled in the study is $10,000 and $500 is attributable to activities performed by Pathology Service and $2,000 to Radiology Service based on the approved cost table, NPC will set aside 25% of each sponsor payment to reimburse to VAMC upon receipt of invoice. These determined percentages will be listed on the Cost Impact form to be reviewed and approved by the R&D Committee.*

*On an ANNUAL/QUARTERLY/MONTHLY basis, NPC will provide the accrued balances listed by service along with a cover letter to VAMC Fiscal Management (or designated recipient determined by the local site) and request a bill of collection.*

*Upon receipt of the bill of collection, NPC will pay the amount due by check to VAMC.*