

Chapter 5 Research Activity Cycle

GRANT SUBMISSION PROCESS

In order to submit a grant to an outside sponsor (including voluntary health organizations, other nonprofits, federal agencies or corporate sponsors), please review the SIBCR Grant Guide for details; information is available on the SIBCR website under Research Grants. The information on the website provides the most complete and up to date information available.

SIBCR must review all grants prior to submission and receive a completed Grant Review Submission form for each project. For projects that require services or subcontracts with other organizations, please submit the materials to SIBCR no less than three weeks or fifteen business days prior to the submission deadline. Shorter times may be acceptable if no other organizations are involved.

For investigator-initiated projects obtaining corporate support, a Cooperative Research and Development Agreement (CRADA) must be established between SIBCR, the corporate partner, and VAPSHCS. Negotiation of CRADAs will be initiated by SIBCR once the investigator has provided necessary information. All such CRADAs must be signed by SIBCR and VAPSHCS. Investigators cannot enter into funding agreements that bind SIBCR or VAPSHCS in any way.

Please note that Veterans Affairs Central Office (VACO) requires that the local VA R&D Committee review proposals being submitted to granting agencies prior to their submission to the sponsor. Principal Investigators submitting grants through SIBCR should submit to the R&D office Pre-Awards Manager the scientific abstract and a completed Grant Review form. For grants submitted through SIBCR, the Grant Review form can be found under the forms section of the SIBCR website.

If an investigator-initiated project is a clinical trial, the investigator must register the trial on the website ClinicalTrials.gov. Please contact the Executive Director for more information.

CLINICAL STUDIES

For clinical studies sponsored by pharmaceutical companies, the investigator should advise SIBCR as soon as the determination to participate is made. Sponsor contact information including name, email, and phone number will be needed. SIBCR will oversee the negotiation and establishment of a CRADA for the project.

SIBCR will also assist with budget review and finalization, including any requirement for human subjects review costs.

When preparing the budget, the investigator and study staff should ensure that all costs for conducting the study will be covered. VAPSHCS must be reimbursed for all services utilized in support of a research project that are in addition to those required for standard patient care. If VAPSHCS services are used (e.g. laboratory, radiology, surgery), the investigator or study coordinator must complete a Research Use Agreement form for each such service line prior to finalizing the study budget, or must obtain an equivalent memorandum of agreement with the relevant service line. By agreement between SIBCR and VAPSHCS, the rate of reimbursement is 90% of the current Medicare charge for a given procedure, unless an exception is formally

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requested and approved. For more information on this, see the section below, "Reimbursing the VA for Clinical Costs".

If the Clinical Research Unit will perform required procedures or otherwise assist in the study, those services should also be included in the budget.

The investigator should ensure that all regulatory and compliance issues are addressed, including possible requirements for an FDA Investigational New Drug application.

POST AWARD

For all research studies, projects cannot be initiated nor any funds expended, prior to VA R&D Committee approval. R&D Committee approval will not be given until all committee and subcommittee reviews and approvals have been secured. This may take up to eight (8) weeks or more if Human Subjects Committee approval is required.

In order to avoid a significant delay in study start up, the approval process should begin as soon as the sponsor notifies the PI and/or SIBCR that a grant or project will be funded.

For studies with corporate funding, generally the CRADA is negotiated at the same time that the project is being reviewed for IRB approval, so that the project will not be delayed. If any other subcommittee approvals are required, they will need to be completed prior to R&D Committee approval.

The following are the relevant committees for approval of research projects as applicable.

- R&D Committee
- Human Subjects Review Subcommittee or Institutional Review Board (IRB)
- R&D Biohazard Committee
- R&D Safety Committee
- Institutional Animal Care and Use Committee (IACUC)
- Recombinant DNA Committee
- Approval of the facility Radiation Safety Officer must be obtained for projects using radioactive compounds or procedures.

After a study has received all required approvals and funding has been received, an SIBCR project account will be opened. The account number will reflect the VA RDIS number assigned after R&D Committee approval.

Funds may be expended from the project account in accordance with the study budget, all relevant guidelines of the sponsor, and SIBCR policy. Financial reports will be provided monthly to members for each project or separate fund.

For all studies that use VAPSHCS clinical resources, the VA Medical Care Appropriation must be reimbursed for any costs incurred for work over and above the standard care required for normal patient care. Study coordinators must ensure that the relevant service lines have current and complete information on actual usage. SIBCR will review projects at least annually to verify that bills of collection have been received for these services in accordance with the Research Use Agreement(s) on file.

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SIBCR will send all required financial reports to sponsors. The principal investigator will be responsible for any scientific progress reports.

REIMBURSING THE VA FOR CLINICAL COSTS

This procedure applies to all extramurally-funded research projects administered by SIBCR, regardless of source (e.g., private industry, voluntary health organizations, NIH or other federal grants). It covers all research projects approved for conduct by VAPSHCS that involve provision of medical care services, such as radiology, cardiology, laboratory medicine, or others as defined by service lines.

Research use of such services consists of:

1. Services provided over and above standard medical care for an eligible veteran;
2. Services provided to a non-veteran participating in a research project (except those provided under 38 CFR §17.85).

Prior to approval of a study, investigators should notify each required service of their intent and seek agreement with them to collaborate in the study. This review and approval will ensure the service has the wherewithal to provide the required study procedures.

At this stage, the investigator or designee should verify the exact CPT or LMIP code for the procedure requested and the charge per procedure. The charge will be the standard rate of reimbursement as set by agreement between SIBCR and VAPSHCS, which is determined to be 90% of the current Medicare rate. Note that Pharmacy and the Clinical Research Unit have separately determined charge schedules that are not encompassed by this procedure.

These written agreements, signed by the service line leader or designee and by the investigator and study coordinator, become a part of the approval packet for the R&D Committee.

After the approved study commences, each providing service must receive a completed Request for Procedure or Test form for each research subject receiving a medical care procedure or test that falls under category 1) or 2) above. On a periodic basis, the service will compile an invoice of charges from research usage and present it to SIBCR for payment.

Rate Exceptions for Medical Service Reimbursement:

Occasionally a research project may be proposed that would significantly further the VA mission but has unusually limited support from its sponsor. If the cost of medical service reimbursement is a specific obstacle to the conduct of such a study, the PI may request a special, project-specific exception to the standard rate.

The PI must prepare a written request for an exception to the rate, describing the particular value of the proposed project to VA patients and VA care, the source of funding and the nature of its limitations, and a justification of the rate that is being requested. The written request will be reviewed by the relevant service line leader, the VAPSHCS Deputy Director or designee, and the SIBCR Executive Director. These individuals will confer with each other and the PI and arrive at a consensus decision as to whether the reduced rate is granted. Such a rate may only be applied to the specific research project for which it was approved, and must be approved prior to the project's submission to the R&D Committee.

STUDY CLOSEOUT

A study account should not be closed in SIBCR prematurely. When the study is completed and all expenditures have been made including for publication costs, the member should inform SIBCR to close the account. Generally, this occurs at the same time as the study is removed from the R&D list of approved projects.

For grants that require final reports to the sponsor, the grant account will not be closed until the final report has been submitted and accepted by the grantor.

Most granting agencies will require return of all unencumbered or unexpended funds. However, requests for no-cost extensions are usually allowed if appropriate scientific rationale is provided. This allows an extension of the grant period and continued use of the project funds.

Sponsors may require requests for no-cost extensions to be received prior to the expiration date of the project. Due dates may vary depending on the sponsor.

If residual funds remain after completion of the project, all expenses have been paid, and there is no requirement by the sponsor to return unexpended funds, these monies may be transferred to a general research account ("zero account"). These funds can be used for general research expenditures within Board-approved policies.