Policy Manual

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5. Research Activity Cycle

Grant Submission Process

In order to submit a grant to an outside sponsor (including, other nonprofits, federal agencies or corporate sponsors), please contact the Executive Director of CARES to discuss appropriate timelines and requirements for submission.

CARES must review all proposals prior to submission. For projects that require services or subcontracts with other organizations, please submit the following materials to CARES (scope of work, budget with justifications, and letter of intent from the participating institution) by the deadline established by the Executive Director.

For investigator-initiated projects obtaining corporate support, a Cooperative Research and Development Agreement (CRADA) must be established between CARES, the corporate partner, and the VA affiliated facility as applicable. Negotiation of CRADAs will be initiated by CARES once the investigator has provided necessary information. All such CRADAs must be signed by the study sponsor, CARES and the Director of the VA facility as applicable. Investigators are not authorized to enter into funding agreements that bind CARES or the VA in any way.

Clinical Studies

For studies sponsored by commercial entities such as pharmaceutical or device companies, the investigator should advise CARES as soon as the determination to participate is made. Sponsor contact information including name, email, and phone number will be needed. CARES will oversee the negotiation and establishment of a CRADA for the project. CRADAs are the contractual vehicle mandated by VA for use in such situations.

CARES will also assist with budget review, negotiations, and finalizations, including any requirement for human subjects review costs.

In preparing the budget, the investigator and study staff should ensure that all costs for conducting the study will be covered. The VA site must be reimbursed for all services utilized in support of a research project when; A) The procedures or processes are not being performed by the investigator or investigator's study team and B) the procedures are considered by the investigator and investigator's supervisor as beyond standard-of-care and C) the procedures are being performed solely for purposes of the research. CARES will review the appropriate paperwork submitted as part of the R&D application to identify if any VA facility services are to be used (e.g. laboratory,

radiology, surgery). CARES will then allocate and reimburse the medical center for the appropriate portion of the income from the study. For more information on this, see the section below, “Reimbursing the VA for Clinical Costs”.

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

If the investigator-initiated project is a clinical trial, the investigator must register the trial on the website ClinicalTrials.gov.

Post Award

For all research studies, research cannot be initiated 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.

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 CARES that a grant or project will be funded.

For studies with private sponsor funding, generally the CRADA is negotiated while 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
- Privacy
- Institutional Animal Care and Use Committee (IACUC)
- Recombinant DNA Committee
- Approval of the facility Radiation Safety Officer needs to be obtained for projects using radioactive compounds or procedures.

Once a study has received all required approvals and funding has been received, a CARES 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 CARES policy. Financial reports will be available at any time on through the CARES website. If unavailable through the website reports will be provided quarterly or upon request. Investigators are expected to manage their funds within the budgeted amounts and review their accounts regularly. CARES should be informed immediately if discrepancies are noted.

CARES 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

For all studies that use VA clinical resources, the VA Medical Care Appropriation must be reimbursed for any costs incurred for work outside the standard of care that have not been performed by the research study staff. CARES has a Memorandum of Understanding in place with its VA affiliated facilities which details the methodology which facilitates this reimbursement. CARES will review projects at least annually to determine the amount due.

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

As required by the R&D Committee, investigators will be complete a Request for Services Form for the appropriate hospital service line which will identify those procedures which meet the following criteria:

1. the procedures or processes are not being performed by the investigator or investigator's study team **and**

2. the procedures are considered by the investigator and investigator's supervisor as beyond standard-of-care **and**

3. the procedures are being performed solely for purposes of the research

This form will be signed by the investigator and the Chief of the hospital service line. CARES will use this information to determine the amount due to the hospital.

Study Closeout

A study account is generally not closed by CARES until the Final Project Data Sheet has been submitted by the investigators and the study status is listed as "Inactive" in the PROMISE database.

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

Some 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 end of 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 by transferred to a general research account ("1000 account") and used by the investigator for general research expenditures. (See Section 3 - Utilization of Funds.)

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