



## CVM Clinical Research Budget Review Process

Due to recent implementation of research pricing and changes to the protocol review processes, Principal Investigators (PIs) conducting any research involving client-owned animals are required by the College to have the associated study budget reviewed and approved by the Blue Buffalo Veterinary Clinical Trials Office (BBVCTO). This is to ensure that budgets are appropriately formulated in accordance with hospital fees, research discounts, and are congruent with both the study protocol and study calendar. A study calendar template and sample budgets are available for use on the [BBVCTO web site](#) (investigator login required to access documents).

All NEW studies involving client-owned animals, or amendments to a currently approved Institutional Animal Care and Use Committee (IACUC) protocol that involves a NEW study/NEW focus (e.g., additional cohort of patients added, new study arm added) must have the budget reviewed by the BBVCTO. Budgets must be evaluated prior to submitting a grant or finalizing an industry sponsored protocol/contract. Budgets funded by other internal sources such as start-up or development funds should be evaluated prior to initiating the IACUC review process to avoid delays in study initiation following IACUC approval.

Following IACUC and budget approval, PIs will register their study with the BBVCTO. Registration is required for both new and amended studies. This is necessary to capture metrics and patient accrual numbers required for yearly reporting to the CVM, Comprehensive Cancer Center (CCC), and Center for Clinical and Translational Sciences (CCTS).

### **Budget Congruency Review SOP**

It is strongly recommended that PIs reach out to the BBVCTO staff **early** in the process of study design:

1. Investigators should submit a [service request for a meeting](#) with the BBVCTO at least 4-6 weeks prior to submitting a grant or during the initial phases of negotiation with an industry sponsored protocol/contract.
  - a. The BBVCTO will respond to the request within 5 business days to arrange a meeting of relevant stakeholders.
2. All study budgets should be submitted to the BBVCTO for [budget review](#) at least 5-10 days in advance prior to submitting a grant or finalizing an industry sponsored protocol/contract. Budgets funded by other internal sources should be submitted prior to initiating the IACUC review process.
  - a. This applies to any NEW study or any AMENDMENT in which a budget has been altered, adds a new study arm, adds a new cohort, or creates a new animal use group within a previously approved IACUC protocol.
  - b. Upload the budget, consent form with a study calendar and/or study protocol outlining the schedule of events.
  - c. BBVCTO staff will review the budget, ensure it is concordant with the consent form and calendar of events/study protocol, and provide comments if needed within 5-10 business days. Additional information or a meeting with the PI may be requested if further clarification is needed.



- d. Failure of the PI to initiate a budget review via the mechanism detailed above will result in delayed grant submission; the ePA-005 (required to apply for external funding) will not be signed until concordance of the budget and proposed study is confirmed. For privately sponsored studies (i.e., industry, etc.), this may also result in a significant delay in study initiation while questions or discrepancies are resolved.

\*\*Clinical research studies submitted for IACUC review without a completed budget review will be flagged and an email sent to the PI indicating the need to follow the review process.

### **Study Registration:**

1. Once a clinical research study has received IACUC approval, the PI should register the study. The PI will receive an email/approval letter from IACUC containing a link for [Study Registration](#). This **MUST** be completed before the study can be initiated.
  - a. Registration will include:
    - i. Primary contact information
    - i. Anticipated start and end date of the study
    - ii. Anticipated number of patients to be enrolled
    - iii. Final study budget, calendar and protocol

Accurate information regarding enrollment numbers in clinical research studies is required by the CVM, CCC, and CCTS. A REDCap survey will be sent out every 3 months to capture updates to this information. The PI must also report animal usage/enrollment in the eProtocol system for yearly IACUC renewals.

2. The PI will receive an email notification indicating the Study Registration is complete.
3. The PI must submit to the VMC Accounting Department a copy of the reviewed budget and study account numbers to provide prepopulated write-off forms that are required for use during performance of the study.

See accounting Write-Off SOP in CVM-Community.

For those studies being managed by the BBVCTO, a meeting will be scheduled prior to study initiation to ensure that all necessary elements are in place and that essential personnel/staff have been appropriately on-boarded.