

VA CENTRAL IRB FEE SCHEDULE

FOR CERTAIN NON-VA FUNDED STUDIES



1. FEES PER STUDY ACTION TO BE REVIEWED

A. INITIAL REVIEW OF PRINCIPAL INVESTIGATOR/STUDY CHAIR (PI/SC) APPLICATION BY CONVENEED IRB

IRB Base Fee ^{1,2} Coordinating Site (PI/SC) (Includes the LSI Application for the PI/SC site if that will be an active recruiting site)	\$3,000.00	<u>Includes review of: (as applicable)</u> <ul style="list-style-type: none"> • Sponsor protocol • Lead/coordinating site (PI/SC) application (VA Form 108) • Investigational Brochure or other pertinent drug or device information • Informed consent templates² (up to 2) • HIPAA authorization templates² • Informed Consent and HIPAA Waivers as needed • VA Form 10-9012 (Drug Information Record) • Recruitment material templates² (flyers, letters, ads, scripts)
Additional Site Fee	\$1,000 / site	For additional local performance sites beyond the PI/SC site
Additional ICF Template Fee	\$600/template	For additional ICF templates ² over the two included in the base fee.

1. Review fees are payable at the time of approval of the sponsor protocol and associated documents. Additional sites may be added and paid for upon completion of review.
2. Informed consent, HIPAA Authorization and Recruitment templates refer to documents that will be consistent across all performance sites, except for local contact information and previously approved local context standard language.

B. INITIAL REVIEW OF PI/SC APPLICATION VIA EXPEDITED REVIEW PROCEDURES

IRB Base Fee ^{1,2} Coordinating Site (PI/SC) (Includes the LSI Application for the PI/SC site if that will be an active recruiting site)	\$2,000.00	<u>Includes initial review of: (as applicable)</u> <ul style="list-style-type: none"> • Lead/coordinating site (PI/SC) application • Sponsor protocol • Investigational Brochure (if applicable) or other pertinent information • Informed consent templates (up to 2) • HIPAA authorization templates • Informed Consent and HIPAA Waivers as needed • Recruitment material templates
Additional Site Fee	\$1,000/site	For additional local performance sites in beyond the PI/SC site
Additional ICF Template Fee	\$500/template	For additional ICF <u>templates</u> over the one included in the base fee.

C. CONTINUING REVIEW			
CR Base Fee ^{3,4} Coordinating Site	\$1,500	<i>Includes review of:</i> <ul style="list-style-type: none"> Current Sponsor protocol Lead/Coordinating Continuing Review Application (VA CIRB Form 115a) All currently approved informed consent templates 	
Additional Site Fee	\$500/site	For additional local performance sites <ul style="list-style-type: none"> Local Site Continuing Review Application (VA CIRB Form 115b) 	
<p>3. Please note that the VA CIRB model uses a common continuing review date for the coordinating site and all local sites based on the date of coordinating site initial approval. This usually results in the first continuing review being less than the full continuing review period for some sites. Subsequent continuing cycles will be for the full review cycle period. New sites can continue to be submitted at any time.</p> <p>4. The Continuing Review Fee is an Annual Fee. In the event, the VA CIRB determines a study requires a continuing review cycle of less than 12 months the CR fees will be payable at the time of each 12-month review.</p>			
D. STUDY-WIDE (PI/SC) AMENDMENTS/CHANGES			
Type of Change ^{5,6,7}	Substantive/Major Requiring Full Board review ⁷	Minor Allowing for Expedited Review ⁷	Notes
With ICF Template Language Revisions ⁷	\$750.00	\$500.00	Includes all documents that are part of the submitted amendment.
Without ICF Template Language Revisions ⁷	\$600.00	\$300.00	
ICF Template Revisions only	\$ 250.00	\$100.00	
Lead Site Investigator or Co-Investigator Change or addition	\$ 200.00	\$100.00	Submit as an amendment using VA Central IRB Form 134a for PI and Form 116 for Co-Is. Includes ICF template update if this is the only other change.
Review of Single Items Outside of Another Revision	\$300	\$100	Review of single documents such as changes in recruitment materials
Other Lead Site Staff changes	No Fee	No Fee	Report at CR (Changes in PIs/Co-PI must be submitted as amendments)
<p>5. This is a single fee for approved changes that are to be implemented at all active local sites. In the event a modification is required for final approval of the change, there is no additional fee for review of the modification if the modification remains consistent with the initial request. If there are multiple rounds of modification requests (e.g. study team not addressing requested modifications) or the modifications returned are substantively different from the initial request additional fees may apply.</p> <p>6. The VA CIRB will generally make the determination of full board or expedited review based on applicable regulations (FDA, VA).</p>			

7. ICF language revisions includes those items that are significant (change in content, context, risk/benefit, etc.) and often require participant reconsent. Insignificant ICF revisions such as spelling/phone number corrections, simple formatting corrections or improvements that do not change content or context are not considered language revisions.

E. OTHER STUDY ACTIONS

Events requiring submission of report for review to the IRB (See VA Central IRB Table of Reporting Requirements⁸)	No Fee	<i>Includes review of:</i> <ul style="list-style-type: none"> • Unanticipated Problems • Protocol Deviations • Noncompliance Reports • Local RCO Audit Reports • DSMB reports/other safety reports
Local Site Amendments⁹	No Fee	Minor amendments specific to one site

8. The VA CIRB assumes each study will incur unanticipated problems, deviations and SAE's in the normal course of the study in direct relation to the study type, number sites and participant accrual. On rare occasions a study may experience an excessive number of these events that are beyond the usual experience for most trials. In these very rare cases, the VA CIRB would like to reserve the right to confer with the sponsor about potential changes to the study, reporting requirements or additional fees for the increased workload.

9. There will be no fee for minor amendments submitted by local sites that are specific to that one site. These include changes in investigators and minor changes to the approved Local Site Investigator (LSI) Application

2. BUDGETING, INVOICING, AND PAYMENT INFORMATION

A. ESTIMATING VA CENTRAL COSTS

The VA lead site (PI/SC site), in cooperation with the sponsor, are responsible for estimating costs of VA CIRB review services for the study. The budget should be based on the applicable line items in the VA CIRB fee schedule with the number of each type of review estimated based on the study design and anticipated review type. Study teams and/or sponsors requesting a variance from the published fee schedule will need to contact the VA CIRB. The estimated IRB budget should be submitted with the PISC application.

In the event a sponsor requires additional certainty regarding the IRB costs for a study, the VA Central IRB is willing to agree to reasonable NTE (not to exceed) costs for the study. The NTE amount should be generous enough to allow for some variations and unexpected events during the anticipated trial period. The VA Central IRB will only charge for the services provided.

It should be noted that local VA Research Offices may require payment of a local fee for cost associated with administrative costs associated with the study. The VA CIRB has no control over these fees and this amount is not included in the NTE agreement.

B. INVOICING AND PAYMENT

The VA Central IRB uses a VA Non-Profit Corporation (NPC) to invoice, receive and manage funds for the organization. The NPC for the VA Central IRB is the **Baltimore Research and Education Foundation (BREF)**. Upon the VA CIRB agreeing to be the IRB of Record for VA sites participating in a non-federally funded study, BREF will contact the sponsor to enter into an agreement regarding the invoicing and payment process.

Upon initial review and approval of the PISC application, the VA Central IRB will notify BREF that the review has been completed. BREF will invoice for the PISC Application within 30 days of receipt of this notice. Review of Local Site Applications and PI/SC amendments will also be invoiced upon completion of the review by the CIRB.

BREF will supply the required payment details in the invoice.