**VA CENTRAL IRB FEE SCHEDULE - 2018**

**FOR NON-FEDERALLY FUNDED CLINICAL TRIALS**



| 1. **GREATER THAN MINIMAL RISK - FULL CONVENED BOARD**
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| 1. **INITIAL REVIEW**
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| **IR Base Fee**1,2Coordinating Site (PISC)Plus 5 Local Performance Sites (LSI) | $20,000.00 | Includes review of:* Sponsor protocol
* Lead/coordinating site (PISC) application (VA Form 108)
* Investigational Brochure (if applicable)
* Informed consent templates3 (up to 3)
* HIPAA authorization templates3
* Informed Consent and HIPPA Waivers as needed
* VA Form 10-9012 (Drug Information Record)
* Recruitment material templates3 (flyers, letters, ads, scripts)
* 1 to 5 local performance sites (LSI)
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|  | **Additional Site Fee** | $2,000 / site | For additional local performance sites over the five included in the IR Base Fee |
| **Additional ICF templates Fee** | $600/template | For additional ICF templates3 over those included in the base fee.  |
| 1. Initial review fees are payable at the time of submission of first set of local site applications. The payment is to include the Initial Review Base Fee, the additional site fees for those over 5 that are planned/anticipated at the initiation of the study and additional consent templates fees (as applicable). Additional sites may be added and paid for upon submission.
2. The IR Base fee will be the fee for precision medicine/distributed enrollment trials where there is only one engaged performance site but recruits, enrolls and monitors participants at multiple other non-engaged locations.
3. 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.
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| 1. **CONTINUING REVIEW**
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| **CR Base Fee**4, 5 Coordinating Site Plus 5 Local Performance Sites (LSI) | $10,000  |  *Includes review of:* * Current Sponsor protocol
* Lead/Coordinating Continuing Review Application (VA CIRB form 104)
* All currently approved informed consent templates
* Up to 5 local performance sites (LSI)
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|  | **Additional sites > 5** | $1,000 / site. | For additional local performance sites over the 5 included in the CR base fee |
| 1. 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 first approval date. This usually results in the first continuing review being less than the full continuing review period for some site. Subsequent continuing cycles will be for the full review cycle period and all sites will be approved on the same date. New sites that are submitted and approved between
2. 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.
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|  **CHANGE FEES FOR STUDY-WIDE TRIALS/SITES REMAINING UNDER CONVENED BOARD**  |
| 1. **STUDY-WIDE**6

Amendments, Revisions, or Modifications to Coordinating Site Application, Sponsor Protocol, Informed Consent Form Templates, Investigational Brochure updates, and/or other materials that apply to all VA sites. |
|  | **Substantive/Major****Requiring Full Board review**7 | **Minor** **Allowing for Expedited Review**7 | **Notes** |
| **With** ICF Template Language Revisions8 | $1,600.00 | $600.00 | Includes **all** documents that are part of the submitted amendment.  |
| **Without** ICF TemplateLanguage Revisions8 | $1,200.00 | $400.00 |
| **ICF Template Revisions only** | $ 400.00 | $200.00 |  |
| **Lead Site Investigator or Co-Investigator** Change or addition  | $ 400.00 | $200.00 | Includes ICF template update if this is the only change. |
| **Review of Single Items outside of another Revision**  | $600 | $200 | Review of single documents for review that are not included as part of another revision or amendment. |
| **Unanticipated Problems/Deviations/****Serious Adverse Events**9 | No Fee | No Fee |  |
| **Lead Site Staff changes (non-PI or Co-I)** | No Fee | No Fee | Report at CR |
| 1. 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.
2. The VA CIRB will generally make the determination of full board or expedited review based on applicable regulations (FDA, VA).
3. 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.
4. The VA CIRB assumes each clinical trial 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 clinical trial 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.
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| 1. **LOCAL SITE AMENDMENTS, REVISIONS, OR MODIFICATIONS**

Local Site Application), LSI/Co-LSI, Local Informed Consent Document, and/or other items related to a single site. |
|  | **Substantive/Major****Requiring** **Full Board review**7 | **Minor** **Allowing for** **Expedited Review**7 | **Notes** |
| **LSI or Co-LSI Addition or Change** | $300.00 | $100.00 | LSI and Co-LSI addition |
| **Study Staff (non-LSI) changes**  | No Charge | No Charge | Most of these can be reported at CR |
| **Items *not consistent* with approved study-wide templates** | $200/item | $200/item | Must also have permission from coordinating site and sponsor. As these changes are not driven by the sponsor the local site may be responsible for these costs. |
| 1. **Study Status Changes/Closure**
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| **Lead Site** | $1,500 (no site limit) |
| **Local Sites** | No Fee |

| 1. **MINIMAL RISK – STUDY MEETS CRITERIA FOR EXPEDITED REVIEW**
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| 1. **INITIAL REVIEW**
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| **IR Base Fee** 1,2Coordinating Site (PISC)Plus 5 Local Performance Sites (LSI) | $10,000.00 | Includes initial review of:* Lead/coordinating site (PISC) application
* Sponsor protocol
* Investigational Brochure (if applicable)
* Informed consent templates (up to 3)
* HIPAA authorization templates
* Informed Consent and HIPPA Waivers as needed for
* Recruitment material templates
* Up to 5 local performance sites (LSI)
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|  | **Additional Site Fee:** | $1,000 / site | For additional local performance sites over the 5 included in the base fee |
| **Additional ICF templates Fee** | $600/template | For additional ICF templates over the 3 included in the base fee. There is no additional per site fee as these are to be implemented at all VA performance sites. |
| 1. Initial review fees are payable at the time of submission of first set of local site applications. The payment is to include the Initial Review Base Fee, the additional site fees for those over 5 that are planned/anticipated at the initiation of the study and additional consent templates fees (as applicable). Additional sites may be added and paid for upon submission.
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.
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| 1. **CONTINUING REVIEW**
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| **CR Base Fee**3,4Coordinating Site + 5 Performance Sites | $5,000 |  *Includes review of:* * Current Sponsor protocol
* Lead/Coordinating Continuing Review Application
* All currently approved informed consent templates
* 5 local performance site
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|  | **Additional sites > 5** | $500.00 | For additional local performance sites over the 5 included in the base fee |
| 1. Please note that the VA CIRB model has a **common continuing review date** for the coordinating site and all local sites based on the date of coordinating site first approval date. This usually results in the first continuing review being less than the full continuing review period. Subsequent continuing cycles will be for the full review cycle period and all sites will be approved on the same date.
2. Continuing review fees are payable at the time of submission of the Coordinating and Local Site continuing review forms (see below). The Full Board CR fees apply to the PISC and local sites.
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| 1. **Amendments to PISC Application, Sponsor Protocol and/or Informed Consent Form Templates**5

Amendments, Revisions, or Modifications to Coordinating Site Application, Sponsor Protocol, Informed Consent Form Templates, Investigational Brochure updates, and/or other materials that apply to all VA sites. |
| **With** ICF Template Language Revisions6 | $600.00 |  |
| **Without ICF Template** Language Revisions6 | $400.00 |  |
| **ICF template Revisions only** | $200.00 |  |
| **Lead Site Investigator (PI) or Co-Investigator (Co-PI)** Change or addition  | $100.00 |  |
| **Review of Single Items outside of another Revision** | $200/item |  |
| **Unanticipated Problems/Deviations/Serious Adverse Events**  | No Fee |  |
| **Lead Site Staff changes (non-PI/Co-PI)** | No Fee |  |
| 1. There is a single fee for the change to be applied at all VA local sites. Approved changes 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.
2. 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.
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| 1. **LOCAL SITE AMENDMENTS, REVISIONS, OR MODIFICATIONS**

Local Site Application, LSI/Co-LSI, Local Informed Consent Document, and/or other items related to a single site. |
| **LSI or Co-LSI Addition or Change** | $100.00 | LSI and Co-LSI addition |
| **Study Staff (non-LSI) changes**  | No Charge | Most of these can be reported at CR |
| **Items *not consistent* with approved study-wide templates** | $200/item | Must also have permission from coordinating site and sponsor. As these changes are not driven by the sponsor the local site may be responsible for these costs. |
| 1. **Study Status Changes/Closure**
 |
| **Lead Site** | $1,000 (no site limit) |
| **Local Sites** | No Fee |

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| 1. **Budgeting, Invoicing and Payment**
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| 1. **VA CIRB Budget**

The VA lead site (PISC) in cooperation with the sponsor are responsible for determining costs of VA CIRB review services for the trial. The budget must be based on the applicable line items in the VA CIRB fee schedule at the time of submission. Total anticipated costs based on good faith estimates of the number of local VA sites, duration of the trial and a reasonable of amendments that may occur during the trial. Study teams and/or sponsors requesting a variance from the published fee schedule will need to contact the VA CIRB. In the event a sponsor requires additional certainty regarding the IRB costs for a trial. The VA Central IRB is willing to agree to reasonable NTE (not to exceed) costs for the trial. The NTE amount should be generous enough to allow for some variations and unexpected events during the anticipated trial period. The VA CIRB 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 trial. The VA CIRB has no control over these fees and this amount is not included in the NTE agreement. The IRB budget should be submitted with the PISC application.  |
| 1. **INVOICING AND PAYMENT:**

The VA CIRB uses a VA Non-Profit Corporation (NPC) to invoice, receive and manage funds for the organization. The NPC for the VA CIRB is the **Baltimore Research and Education Foundation (BREF)**. Upon submission of the PISC application the VA CIRB will notify the BREF that the application has been received along with the anticipated number of sites for the trial. BREF will invoice for the PISC and any LSI in excess of five within 30 days of receipt of this notice.BREF will supply the required payment details in the invoice.  |