Single IRB Fees

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The single IRB (sIRB) mandate is a set of harmonizing federal policies that require certain types of federally-funded studies that involve multiple institutions/sites to use a single IRB to accomplish IRB review and approval for all of the institutions. This information may also be useful for multi-site studies that are not federally-funded but that wish to use a single IRB.

Federally Sponsored Studies

Effective January 25, 2018, the NIH has determined that IRB Fees related to the sIRB mandate may be charged as a direct cost.

VCU IRB has developed a fee structure based on the effort required to conduct IRB review for sites that rely on the VCU IRB While the NIH mandate is effective January 25th, 2018, the VCU IRB fee structure is effective June 2018. The new fees apply to new or competing grants or contracts that are due on or after June 5th, 2018.

These fees should be incorporated into the grant or contract budget when conducting multi-site trials where VCU will be the IRB of record. Per the **NIH policy**, the additional costs associated with sIRB review should be charged to grants or contracts as direct costs, provided that such costs are well justified and consistently treated as either direct or indirect (F&A) costs at VCU. *Ongoing, noncompeting awards will not be expected to comply with the policy until a competing renewal application is submitted.*

The approved fee to recoup expenses for each site relying on VCU sIRB review is $437 in the first year, and $317 for each subsequent year. Costs may vary depending on the services needed by each site. If your site is targeting federally regulated vulnerable populations such as prisoners or wards of the state, or is otherwise complex to the extent that additional review may be needed, please contact IRBreliance@vcu.edu for guidance.

For information about sIRB review, go to the Reliance section of the VCU IRB website.

sIRB Fees and Grant Budget Scenarios

Scenario #1

A VCU PI prepares an NIH grant application which is a multi-site study (non-exempt) in which VCU, University of Michigan (UM), Emory (EU), and Johns Hopkins (JH) will collaborate. The grant will be submitted to the NIH in June 2018.

The VCU PI will need to contact the collaborating investigators to see if they want to participate in the project, and discuss the possibility of VCU's IRB of being the IRB of record. The VCU PI and the investigators at UM, EU, and JH should each contact their IRB offices to see if this arrangement is agreeable. If all agree, then the VCU PI will let the VCU Office of Research Subjects Protections know that IRB reliance agreements will be needed with U M, EU, and JH for this protocol. To request a reliance arrangement with VCU's OHRP, please email irbreliance@vcu.edu.

In the NIH grant application, the VCU PI outlines the plan for VCU IRB to be the sIRB, and that UM, EU, and JH will rely on VCU IRB. In this scenario, VCU is the primary awardee and the sIRB, so primary activities are **charged within VCU's indirect costs** as part of the F&A rate, while the secondary review activities for UM, EU, and JH may be charged as VCU's direct costs, which will be $437 in the first year and then $317 for each subsequent year.

Protocol #1: VCU, UM, Emory, and Johns Hopkins

Year 1
$0 for protocol and VCU site.
$437 per each external site

EACH subsequent year
$0 for protocol and VCU site.
$317 for each external site.

Scenario #2

A VCU PI prepares an NIH grant application which is a multi-site study (non-exempt) in which VCU, University of California-San Francisco (UCSF), Cleveland Clinic (CC), and University of Miami Med Ctr (UMMC) will collaborate. The grant will be submitted to the NIH in June 2018.

The VCU PI will need to contact the collaborating investigators to see if they want to participate in the project, and discuss that VCU PI would like the Cleveland Clinic IRB (CC IRB) to the IRB of record, and the other investigators agree. The VCU PI and the investigators at UCSF, CC, and UMMC should each contact their local IRB offices to see if this arrangement is agreeable. To request a reliance arrangement with VCU's OHRP, please email irbreliance@vcu.edu.

In the NIH grant application, the VCU PI outlines the plan for CC IRB to be the sIRB, and that VCU, UCSF, and UMMC will rely on CC IRB. In this scenario, VCU is the primary awardee, so all IRB activities are **charged as VCU's direct costs on the grant budget**, which will be the **CC's rate for initial and annual reviews**. The CC will bill the VCU PI for the IRB costs and the VCU PI will charge the amount directly to the grant.

Protocol #2: VCU, UCSF, UMMC and CC

VCU PI must contact CC for the rates to insert into the budget and to get a letter of agreement to rely on the CC IRB. IRB Reliance and Reviewing Agreements will be made prior to the commencement of human subjects review.