HRP-833 | 08/07/2025

**WORKSHEET: Considerations for Serving as the sIRB**

The purpose of this worksheet is to provide information on considerations that the institution will evaluate when considering requests for the institution’s IRB to serve as single IRB of record for multi-site or collaborative research.

1. **General Exclusion Criteria**

The following are circumstances in which VCU may not serve as the sIRB for a multisite study.

☐ The institution is not listed as the prime awardee of federal grant.

☐ The study is not funded.

☐ The study is commercially sponsored.

☐ The institution is not engaged in the research activities.

☐ The study is prohibited from reliance by any state or local law limitations.

☐ The study is determined to be Exempt.[[1]](#footnote-1)

☐ The study is determined to not involve Human Research.

1. **Study Considerations for Serving as sIRB for other institutions**

VCU will evaluate on a case-by-case basis serving as the sIRB. The following characteristics of the study will be evaluated to determine whether VCU and study team can adequately support and oversee the research.

☐ Complexity of protocol/risk level of study

Comments: Click or tap here to enter text.

☐ Number, type and location of participating sites

Comments: Click or tap here to enter text.

☐ Principal Investigator experience

Comments: Click or tap here to enter text.

☐ Study team is adequately resourced and prepared to facilitate the multi-site study

Comments: Click or tap here to enter text.

☐ Participating site(s) are adequately resourced and prepared to participate in the multi-site study

Comments: Click or tap here to enter text.

☐ FDA regulated research activities are included in the study

Comments: Click or tap here to enter text.

1. **Additional Considerations for Serving as sIRB**

The following are additional considerations for evaluating VCU’s ability to serve as the sIRB for a multisite study.

☐ VCU’s IRB has sufficient expertise and resources to conduct the IRB review

Comments: Click or tap here to enter text.

☐ The VCU’s HRPP has sufficient expertise and resources to establish and manage multiple participating sites.

Comments: Click or tap here to enter text.

☐ VCU’s HRPP Stakeholders (Sponsored Projects Administration, Quality Assurance Program, etc.) have adequate resources to support or monitor the research activities

Comments: Click or tap here to enter text.

☐ Ability for VCU to comply with the relevant local context considerations of the participating site(s)

Comments: Click or tap here to enter text.

☐ Preference to outsource sIRB function to an external IRB

Comments: Click or tap here to enter text.

☐ Other relevant considerations (e.g., vulnerable populations, conflicts of interest, costs, etc.)

Comments: Click or tap here to enter text.

1. **Additional Considerations for Serving as sIRB for a DOD institution**

The following are additional considerations for evaluating VCU’s ability to serve as the sIRB for a DOD institution (DoDI 3216.02 section 3.5).

☐ VCU has a current federal assurance of compliance

Comments: Click or tap here to enter text.

☐ VCU’s IRB is registered in accordance with Subpart E of 45 CFR 46

Comments: Click or tap here to enter text.

☐ There is a process for the DOD institution to review the protocol to ensure all applicable local and DOD requirements are addressed in the protocol

Comments: Click or tap here to enter text.

☐ VCU’s IRB will apply the DOD requirements specified in DoDI 3216.02, including but not limited to non-DOD institutional responsibilities defined under DoDI 3216.02 section 3.6(b)

Comments: Click or tap here to enter text.

☐ If the research constitutes classified human participant research, the COHRP must approve the reliance agreement

Comments: Click or tap here to enter text.

1. **Additional Considerations for Serving as sIRB for VA Research**

The following are additional considerations for evaluating VCU’s ability to serve as the sIRB for VA research.

☐ VCU’s IRB must meet all the IRB requirements described in 38 CFR Part 16

Comments: Click or tap here to enter text.

☐ When the IRB of Record is directly operated and supported by a non-VA entity, the policies and procedures related to the review of VA research by the non-VA entity must be consistent with VHA Directive 1200.05, 1005.01, and all requirements applicable to VA research

Comments: Click or tap here to enter text.

☐ VAs may rely upon the VHA Central Office IRB (VA Central IRB), an IRB of another VA facility, the IRB(s) of a medical or dental school, or the IRB of another federal agency. A VA facility may also use an IRB for multi-site protocols that has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facilities

Comments: Click or tap here to enter text.

☐ A VA will permit the use of a commercial IRB as an IRB of Record if it has been specifically designated by ORD as a commercial IRB that may serve as an IRB for cooperative research

Comments: Click or tap here to enter text.

☐ A Memorandum of Understanding (MOU) or Authorizing Agreement must be established and signed

Comments: Click or tap here to enter text.

☐ VCU’s IRB must hold current IRB registrations with FDA/OHRP and provide updates to membership as required by VHA Handbook 1058.03 and the institution has a current federal assurance of compliance

Comments: Click or tap here to enter text.

1. For a HHS funded or supported, non-exempt collaborative research study involving human subjects, any site that is engaged must rely on the sIRB for review. If the research as a whole is non-exempt and an institution is engaged in the research (even if their portion of the research is exempt), then the institution must rely on the sIRB. *(Correspondence with OHRP, September 27, 2022)*. [↑](#footnote-ref-1)