HRP-832 | 08/07/2025

**WORKSHEET: Considerations for Relying on an External IRB**

The purpose of this worksheet is to provide considerations that the institution may evaluate when considering requests to outsource review to a commercial IRB or to require a pSite’s IRB to serve as sIRB.[[1]](#footnote-1) The HRPP Director may determine (in consultation with other institutional stakeholders as appropriate) that the use of an external IRB is appropriate for the research even if the considerations below do not apply.

1. **General exclusion Criteria**

The following are circumstances in which the institution will generally not rely on an external IRB, unless authorized by the HRPP Director.

☐ The study qualifies as a Veterans Administration (VA) study (e.g., veterans will be enrolled, the PI conducts the research under a VA appointment, VA facilities will be used).[[2]](#footnote-2)

☐ The institution is not engaged in the research activities.

☐ The study is investigator initiated and involves the use of IND/IDE held by VCU.

☐ The study is being conducted by a student/is a classroom project.

☐ The study is determined to not involve Human Research.

☐ The study is determined to be Exempt. [[3]](#footnote-3)

1. **Considerations** **to Rely on a Commercial IRB**

The institution will evaluate on a case-by-case basis ceding IRB review. The following characteristics of the study will be evaluated to determine whether to rely on a Commercial IRB (e.g., Advarra, WIRB, etc.). (At least one of the following considerations should be true)

☐ The project is commercially sponsored research.

☐ The institution’s IRB lacks sufficient expertise or resources to conduct the IRB review.

☐ The institution is the lead site of a Multi-Site Study and the institution has elected to use a commercial IRB for the review of the study.

☐ Other relevant considerations: Click or tap here to enter text.

1. **GENERAL CONSIDERATIONS FOR RELYING ON ANOTHER (NON-COMMERCIAL) IRB**

The following are additional considerations for evaluating the institution’s willingness to rely on an external IRB with a valid OHRP-approved Federalwide Assurance (FWA). (At least one of the following considerations should be true.)

☐ Relying on an external IRB is mandatory.

Comments: Click or tap here to enter text.

The reviewing IRB has sufficient expertise and experience reviewing and overseeing research of similar nature to the proposed study.

Comments: Click or tap here to enter text.

☐ The reviewing IRB has sufficient expertise with certain features of the protocol or the participant population that may pose special concerns. (e.g., recruitment of socially or economically disenfranchised populations, local cultural mores or unique clinical circumstances)

Comments: Click or tap here to enter text.

☐ Whether relying on an external IRB review could create or mitigate unique institutional risks, such as conflicts of interest.

Comments: Click or tap here to enter text.

☐ Implications for VCU of the decision, including:

a) analysis of lost research opportunities (i.e., unwillingness of a sponsor or funder to allow local, non-relying IRB review);

b) the additional administrative time and costs associated with establishing authorization agreements.

Comments: Click or tap here to enter text.

☐ Resources needed by the study team to learn and adhere to the policies and procedures of the reviewing IRB.

Comments: Click or tap here to enter text.

1. This document satisfies AAHRPP element I-9 [↑](#footnote-ref-1)
2. ORD policy requires that the VA Medical Center Director request approval from the Chief Research and Development Officer (CRADO) approval when the VA facility wants to establish a new HRPP, change its IRB(s) of Record, or wants its internal IRB to serve as an IRB of Record for a non-VA entity if allowed by ORD policy. See [IRB Relationships in the VA: Single IRB Exceptions, Independent (Commercial) IRBs, and changing IRB reliance by the VA Facility](https://www.research.va.gov/programs/orppe/irb_relationships.cfm). [↑](#footnote-ref-2)
3. 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-3)