HRP-833 | 2/2/2024

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 the institution 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 federally funded (PI does not anticipate NIH or federal funding).

☐ The study is commercially sponsored.

☐ The institution is not engaged in the research activities.

☐ The study is determined to be Exempt[1].

☐ The study is determined to not involve Human Research.

2. Study Considerations for Serving as sIRB for other institutions

The institution will evaluate on a case-by-case basis serving as the sIRB. The following characteristics of the study will be evaluated to determine whether the institution 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.

[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)*.

☐ FDA regulated research activities are included in the study.

Comments: Click or tap here to enter text.

3. Additional Considerations for Serving as sIRB

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

☐ The institution's IRB has sufficient expertise and resources to conduct the IRB review.

Comments: Click or tap here to enter text.

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

Comments: Click or tap here to enter text.

☐ The institution'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 the institution 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.

4. Additional Considerations for Serving as sIRB for a DOD institution

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

☐ The institution has a current federal assurance of compliance.

Comments: Click or tap here to enter text.

☐ The institution'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.

☐ The institution'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.