

WORKSHEET: Considerations for Serving as the sIRB

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13.203 (HRP-833)	11/21/2024	1 of 1

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. This worksheet may be used as a working document for the Reliance Administrator or IRB staff during the process of evaluation and may be saved until a determination has been made.

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 institution is not the prime awardee, the lead PI/site will be responsible for identifying the sIRB, such as an accredited IRB from a designated pSite or a commercial IRB-
Comments: Click or tap here to enter text.
- 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
- 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.
- 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 to conduct the IRB review -
Comments: Click or tap here to enter text.
- 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 a commercial 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.